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United States Patent [19]

Cone et al.

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[45] Date f Patent: Apr. 10, 1990

[54] MICRO-INJECTION PORT

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[73] Assignee: C. R. Bard, Inc., Murray Hill, N.J.

[21] Appl. No.: 151,406

[22] Filed: Feb. 2, 1988

[51] Int. Cl.[4] A61M 5/00

[52] U.S. Cl. 604/93; 604/175

[58] Field of Search 604/93.86, 8-10, 604/175, 891.1, 244

[56] References Cited

U.S. PATENT DOCUMENTS

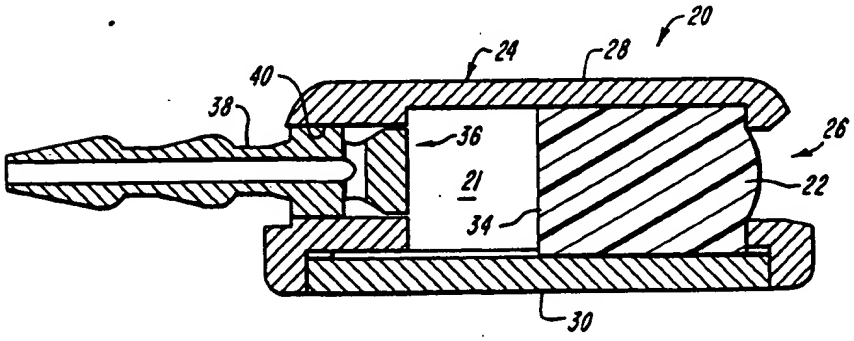
3,310,051	3/1967	Schulte	128/216
3,613,663	10/1971	Johnson	128/2 R
4,181,132	1/1980	Parks	128/399
4,190,048	2/1980	Sampson	128/215
4,464,178	8/1984	Dalton	604/174
4,479,798	10/1984	Parks	604/4
4,496,343	1/1985	Prosl et al.	604/86
4,543,088	9/1985	Bootman et al.	604/93
4,569,675	2/1986	Prosl et al.	604/175
4,604,090	8/1986	Reinicke	604/118
4,692,147	9/1987	Duggan	604/93
4,710,167	12/1987	Lazorthes	604/93
4,710,174	12/1987	Moden et al.	604/175
4,767,410	8/1988	Moden	604/175
4,781,695	11/1988	Dalton	604/175

Primary Examiner—Stephen C. Pellegrino

[57] ABSTRACT

A micro-injection port having a low profile is provided. The micro-injection port has a septum and an injection chamber located side-by-side. When implanted, the puncture surface of the septum lies substantially perpendicular to the surface of the skin. The micro-injection port also has a filter system. The filter is formed from an opening in the side wall of the injection port and a shaft secured within the opening.

23 Claims, 5 Drawing Sheets



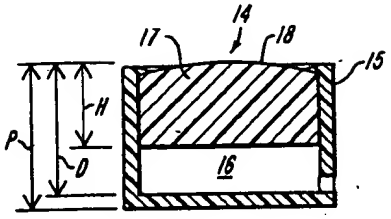


FIG. 1A

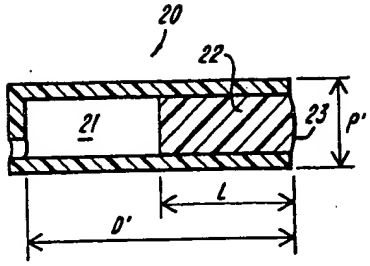


FIG. 1B

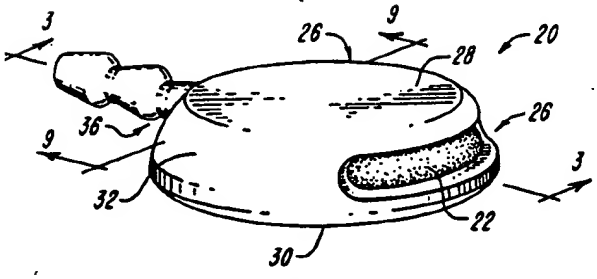


FIG. 2

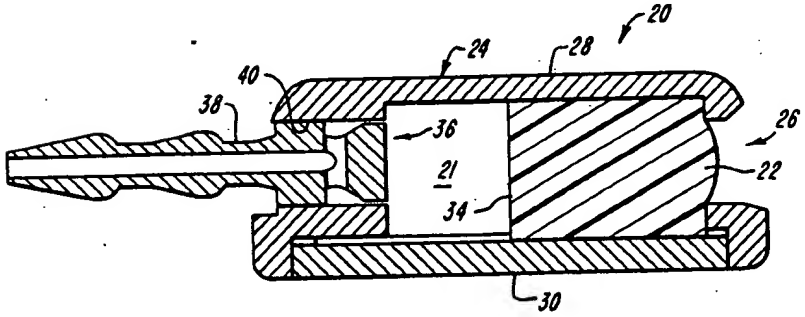


FIG. 3

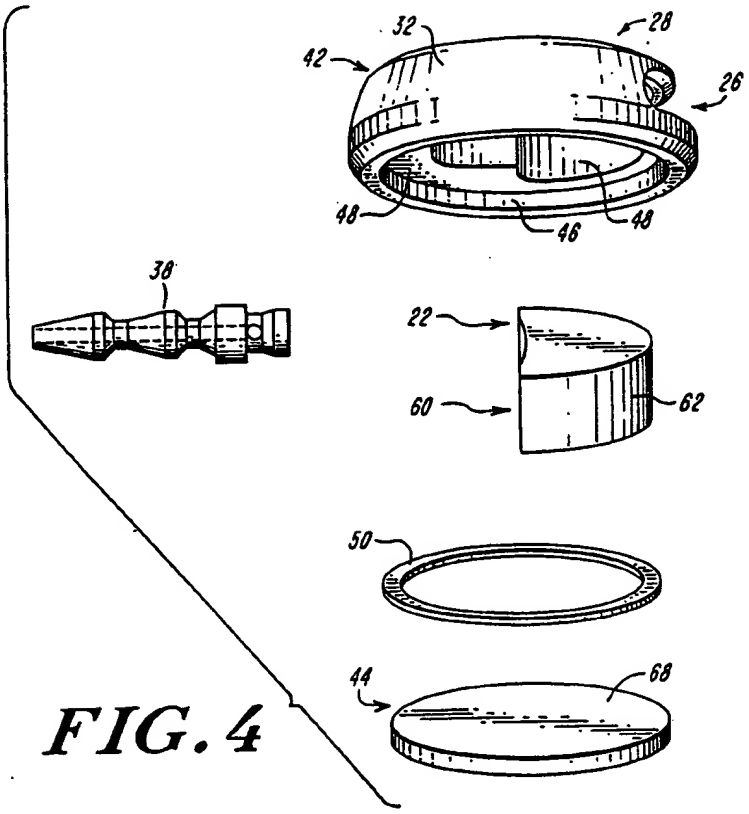


FIG. 4

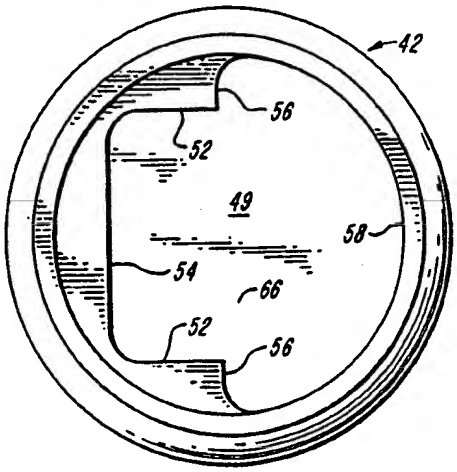


FIG. 5

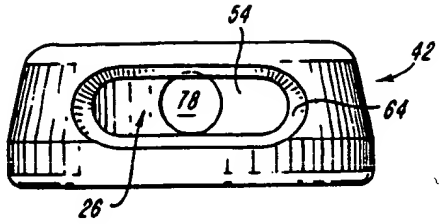


FIG. 6

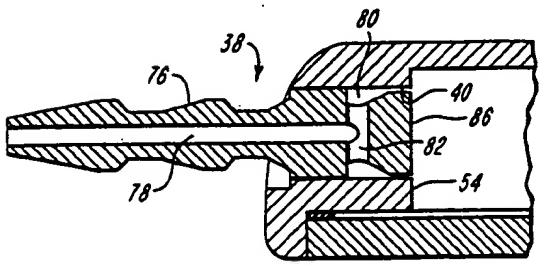


FIG. 7

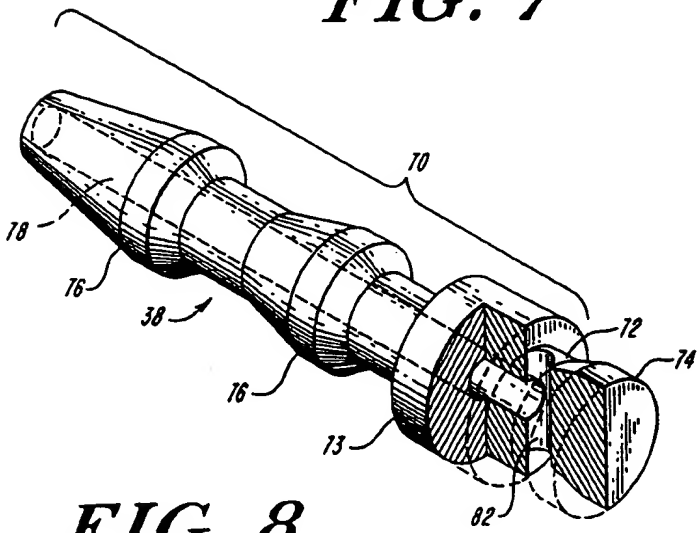


FIG. 8

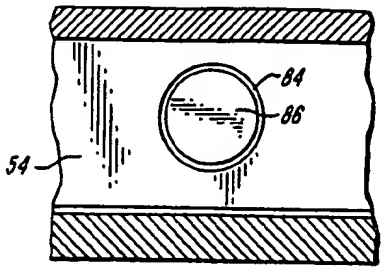


FIG. 9

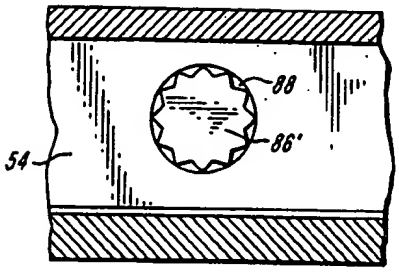


FIG. 11

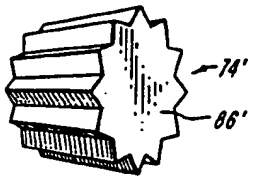


FIG. 10

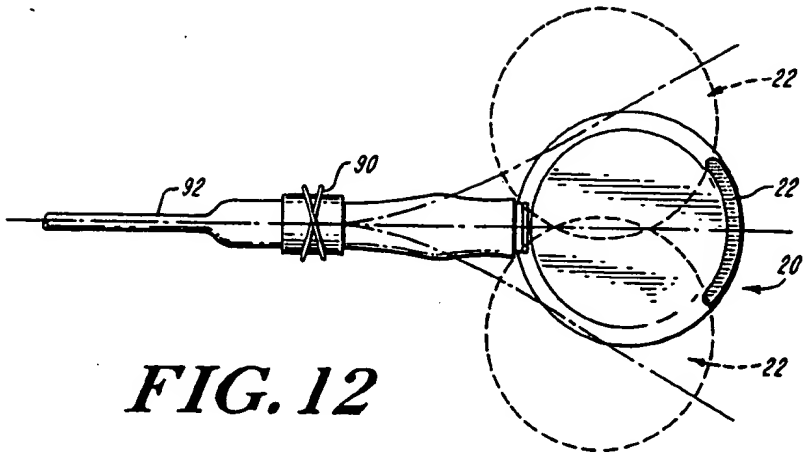


FIG. 12

FIG. 13A

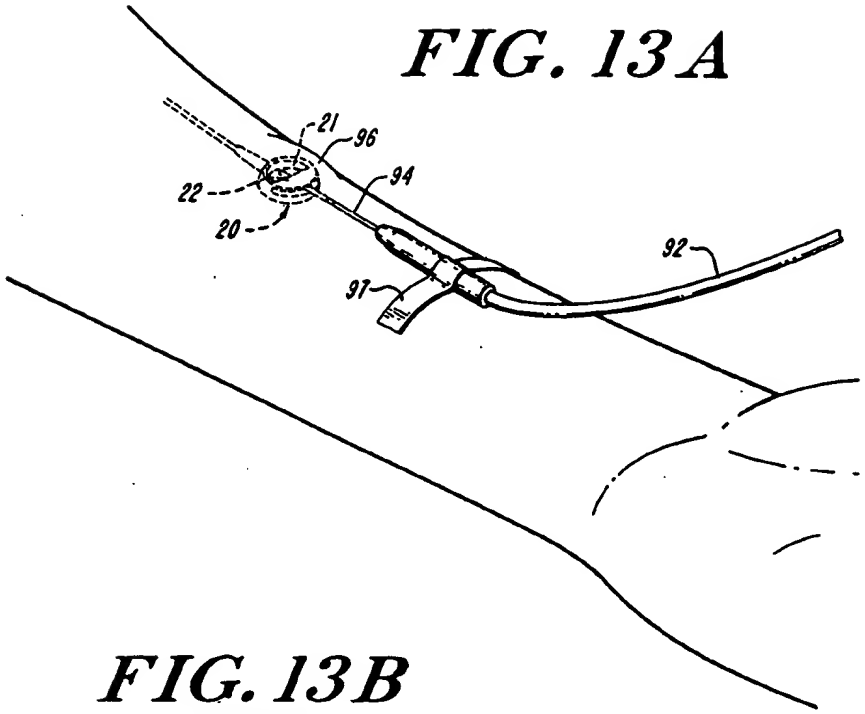
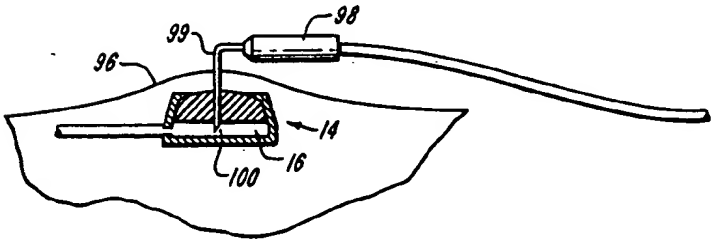


FIG. 13B
(PRIOR ART)



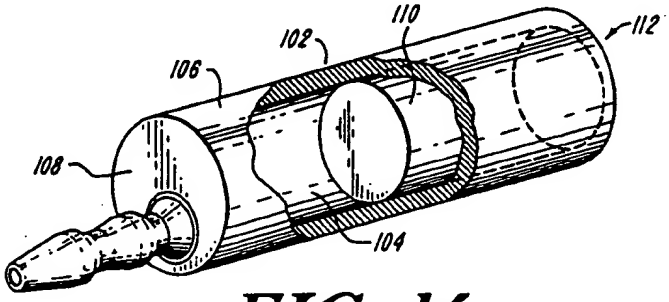


FIG. 14

MICRO-INJECTION PORT

BACKGROUND OF THE INVENTION

This invention relates to subcutaneously implanted injection ports, filter systems for such ports and methods of implanting such ports.

A subcutaneous injection port is a totally implantable device designed to provide repeated access to a body space such as the vascular system. Injection ports typically include an injection chamber accessible through a septum, the injection chamber being connected by an exit port and catheter to the desired body space. The device is implanted just beneath the skin, and the injection chamber may be accessed repeatedly by passing a needle through the skin and septum.

Currently marketed subcutaneous injection ports typically are top-entry devices. In a top-entry device, the septum is stacked on top of the injection chamber, and the puncture surface of the septum is located parallel to the skin when implanted. The injection chamber is accessed by passing a needle through the skin perpendicular to the septum and skin. Such perpendicular access requires a relatively tall device because the injection chamber must be deep enough to accept the needle opening and the septum must be thick enough to insure a leakproof seal after repeated punctures. While such relatively tall top-entry devices are useful in certain instances in adults, they can only be scaled down a certain amount and are not so useful in pediatric patients or in particular locations in other patients where a tall device may result in tissue damage.

Another drawback of top-entry devices is that specially designed right-angle needles are usually used when long-term infusion is contemplated. The distal end of the right angle needle is inserted through the skin and septum and into the injection chamber of the top-entry device, with the proximal end of the needle lying parallel to the skin. This proximal end then is taped to the skin to secure the needle in place. These right-angle needles are known to back out of the chamber due to movements by the patient. Further, the length of the distal end of the right-angle needle must be closely matched to the depth of the implanted port. This sometimes requires trial and error of different sized needles with repeated puncture of the skin. Such repeated puncture is undesirable.

Another drawback of the top entry device is that when semi-rigid catheters are used for long-term access, special anti-kink brackets are required to allow the catheter which exits perpendicularly to the skin to be bent over and taped to the skin without kinking.

Another drawback of typical top-entry devices is that expensive non-coring needles, such as a Huber-type needle, must be used when accessing the injection chamber via the septum. The septums of such devices are relatively wide and have a short puncture length relative to the width. To allow repeated puncture, the septum must be captured under substantial compression. The compression is of a degree that a standard needle would core the septum.

Further, implanted ports sometimes flip over. Flipping is particularly likely with small devices. The overturning of the prior art top-entry devices renders their septum inaccessible.

It is desirable to use a filter in a subcutaneous injection port t prevent particles introduced into the port s chamber from entering into the body space accessed by

the chamber. For example, particles of fat, skin, dust, rubber and plastic sometimes are introduced into the injection chamber of the implanted port as a needle is passed into and through the skin and septum to access the chamber. The anger to the patient from such particles is of increased concern in pediatric patients whose relatively smaller body passages may become blocked more easily than the larger passages of adults. Therefore, a pediatric injection port not only should have a low profile, but also should have a filter. However, manufacturing a filter for an injection port as small as the device of the present invention is problematic.

SUMMARY OF THE INVENTION

The micro-injection port of the invention has a septum and injection chamber located side-by-side, rather than stacked on top of one another. When implanted, the puncture surface of the septum lies substantially perpendicular to the surface of the skin, rather than parallel to the surface of the skin as in the top-entry devices. This side-by-side arrangement substantially reduces the height of the device making the device useful in small children or infants, or in places in adult patients where the skin is not protected by fatty tissue. The reduced height or low profile of the side-entry injection port also renders the device more desirable from a cosmetic point of view when implanted.

While the foremost advantage of the side-entry injection port is its decreased height, the device has many other advantages. Because the puncture surface of the septum is located on the side of the device and oriented substantially perpendicular to the surface of the skin, if the device flips over, the septum still is accessible. Likewise, this side placement of the septum allows for long-term access of the injection chamber using a straight needle. According to the invention, a needle is passed substantially parallel to the surface of the skin, through the skin and septum and into the injection chamber. The portion of the straight needle outside the skin lies substantially parallel against the surface of the skin. It, therefore, is easy to secure the needle in place flat against the skin simply by taping it. Relative motion between the skin surface and muscle fascia does not result in accidental needle withdrawal because the relative motion is perpendicular to the plane of injection. Moreover, a right angle needle is not required and, therefore, it is not necessary to closely match the length of the needle to the depth of the implanted port. Further, a standard needle, rather than a special non-coring needle may be used because the puncture length of the septum is relatively long and the septum is captured under relatively low compression.

The side-entry injection port has a rigid housing with rigid walls defining an injection chamber. The housing may have a substantially flat top wall, a substantially flat bottom wall and a side wall connecting the periphery of the top and bottom walls. Preferably the housing is in the shape of a disk, with the top and bottom walls being concentric and the bottom wall being slightly larger than the top wall to stabilize the device against flipping. The side wall has an opening and a septum is captured by the housing to seal the opening. The exposed puncture area of the septum occupies a substantial portion of the projected sidewall area of the housing when viewed along the centerline of the septum. An exit port located opposite the septum communicates with the injection chamber through the side wall.

The side-entry injection port has a filter system to prevent particles introduced int the injection chamber from entering the body. The filter is formed from an opening in the side wall of the housing and a shaft secured within the opening. A first portion of the shaft is sized to sealingly mate with the opening and the second portion of the shaft has a cross-sectional area less than the cross-sectional area of the opening at or close t the inside surface of the side wall. The second portion of the shaft and the opening define a space. The smallest cross-sectional area of this space defines the filter. The space communicates with an exit bore through the shaft such that fluid introduced into the injection chamber may exit the injection chamber by passing into the space and out the exit bore.

Preferably the shaft has a barbed portion extending from the side wall of the injection port for a catheter attachment site. Thus, the shaft and the opening in the side wall of the housing together act as a filter, an exit port and a catheter attachment site. Preferably, a suture tab is secured to the barbed portion of the shaft. The suture tab is sutured to the tissue when the device is implanted and the device may be rotated somewhat about the axis defined by the suture point.

It is an object of the invention to provide a device having the foregoing features and it is a further object of the invention to provide such a device that is easy to manufacture and has few parts.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 2A is a schematic cross-sectional representation of the injection port of the prior art;

FIG. 2B is a schematic cross-sectional representation of the injection port of the invention;

FIG. 2 is a side elevated view of the preferred embodiment of the invention;

FIG. 3 is a cross-sectional view along lines 3—3 of FIG. 2;

FIG. 4 is an exploded view of FIG. 2;

FIG. 5 is a bottom view of the top element of FIG. 4;

FIG. 6 is a front view of the top element of FIG. 4;

FIG. 7 is an enlarged view of the exit port ion of FIG. 3;

FIG. 8 is an enlarged cross sectional view of the port outlet connector of FIGS. 3 and 4;

FIG. 9 is a cross-sectional view along lines 9—9 of FIG. 2;

FIG. 10 is a side view of the head and neck region of another embodiment of the port outlet connector of the invention;

FIG. 11 is a cross-sectional view similar to FIG. 9 using the device of FIG. 10;

FIG. 12 shows the attachment of the injection port of the invention by a suture tab allowing limited rotation of the device when implanted;

FIG. 13A is a schematic representation of the side-entry port of the invention implanted beneath the skin;

FIG. 13B is a schematic representation of the typical prior art device implanted beneath the skin;

FIG. 14 shows another embodiment of the side-entry port of the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

The injection port of the invention is schematically shown in cross-section and compared to the prior art in FIG. 1. The typical prior art device is a top-entry injection port 14 having a rigid housing 15 defining an injection chamber 16 accessible through septum 17. In a top-entry injection port 14, the septum 17 is stacked on top of the injection chamber 16. When implanted, the puncture surface 18 of the septum is located substantially parallel to the surface of the skin and the height or profile P of the device is defined at a minimum by the height of the injection chamber 16 *plus* the height of the septum 17.

The side-entry injection port 20 of the invention places the injection chamber 21 and the septum 22 side-by-side, rather than stacked on top of one another. When implanted, the puncture surface 23 of the septum 22 is located substantially perpendicular to the surface of the skin, and the profile P' of the device is defined by the height of the septum, not the height of the septum added to the height of the injection chamber. Because the profile is substantially reduced as compared to the prior art top-entry devices, the invention is useful in environments in which top-entry devices are not useful.

The invention's side-entry arrangement also allows for increasing the useful life of the septum without increasing the height of the septum and, correspondingly, the height of the device. The useful life of the septum may be increased by increasing the puncture length of the septum. The puncture length of the septum may be defined by the distance of the septum through which a needle must travel to access the injection chamber. Generally, the longer this distance, the greater the number of punctures the septum can withstand without leaking.

In a top-entry device, the puncture length corresponds to the height H of the septum 17. If this puncture length or height H is increased, then so is the overall profile P of the device. In the side-entry injection port of the invention, the puncture length corresponds to the length L of the septum 22, the length running parallel to the surface of the skin. If this puncture length L is increased, then only the overall length of the device is increased. The height or profile P. of the device remains the same.

The side-entry injection port of the invention may be distinguished from the prior art in another respect. In the top-entry injection port of the prior art, the distance D from the puncture surface 18 of the septum to the wall of the injection chamber opposite the septum 17 is always less than the profile P of the device. In the side-entry port of the invention, the distance D. from the puncture surface 23 of the septum 22 to the wall of the injection chamber opposite the septum 22 may be much greater than the profile P of the device. In fact, the puncture length L of the septum 22 alone may be greater than the profile P' of the device.

Referring to FIGS. 2 and 3, the preferred embodiment of the invention is a side-entry injection port 20 having a housing 24 shaped substantially like a disk. The housing 24 is made of a rigid material, such as metal, and defines an internal injection chamber 21 accessible through an opening 26 in the housing 24, which opening 26 is sealed by the septum 22. A biocompatible metal is preferred over plastic because a metal housing generally requires thinner walls to achieve the desired rigidity and compression on the septum. An implant grade Titanium alloy has been used successfully.

The housing 24 preferably has flat, parallel disk-shaped top and bottom walls, 28 and 30, respectively, which walls are connected along their periphery by a side wall 32. The top and bottom walls 28, 30 are concentric with the top wall 28 somewhat smaller than the

bottom wall 30. The side wall 32 slopes gently from the periphery of the top wall 28 to the periphery of the bottom wall 30. Preferably, the device has rounded corners to minimize tissue irritation when implanted. The top, bottom and side walls 28, 30, 32 along with chamber-facing surface 34 f the septum 22 together define the injecti n chamber 21.

The opening 26 is in the side wall 32 of the housing 24 and is sealed off by the septum 22. The opening 26 extends approximately 80° around the circular side wall 32. The remainder of the side wall 32 is solid, except for an exit port 36, which exit port provides an exit path for fluid introduced into the injection chamber 21.

The exit port 36 communicates with the injection chamber 21 and is located in the side wall 32 opposite the septum 22. The exit port 36 in the preferred embodiment is defined by a port outlet connector 38 fitted into a bore 40 in the side wall 32 of the housing 24. The port outlet connector 38 and the bore 40 in the side wall 32 together serve as a filter system, an exit port and a catheter attachment site for the side-entry injection port 20 of the invention. These features are discussed in greater detail below.

The low profile injection port 20 is shown in an exploded view in FIG. 4. The rigid housing 24 is constructed from two separate elements, a top element 42 and a bottom element 44. The top element 42 defines the top wall 28 and the side wall 32 of the injection port 20. A lip 46 extends about the periphery of the side wall 32 to form a seat or step 48 also extending completely about the periphery of the side wall 32. The step 48 is parallel to the top wall 28 and is provided to mate in face-to-face relation with the bottom element 44 when the device is assembled. The bottom element 44 is sized to fit just within the lip 46.

The top and bottom elements 42, 44 capture a gasket 50 and the septum 22. The gasket 50 is sized to fit within the lip 46 and between the facing surfaces of the bottom element 44 and the step 48. The gasket 50 is essentially a silicone rubber ring and is captured between the top and bottom elements to form a leak-proof seal.

The top element 42 has a hollowed out center 49. Referring to FIG. 5, the hollowed out center has the profile of a doorknob. There is a neck region and a head region. The neck region has neck side walls 52 connected at one end by a neck base wall 54. The head region defines a shape similar to a slice of a disk. The head region has two shoulder walls 56, one each extending perpendicularly from each of the neck side walls 52, and has an arcuate front wall 58 connecting the free ends of the shoulder walls 56.

The septum 22 is sized to fit compressively within the head region. Referring to FIG. 4, the septum also is shaped similar to a slice of a disk, having a chamber-facing wall 60 and an arcuate septum front wall 62. The septum front wall 62 mates with the arcuate front wall 58 of the head region and the ends of the chamber-facing wall 60 mate with the shoulder walls 56 of the head region.

The opening 26 in the top element 42 is shown in detail in FIG. 6. The opening 26 has a beveled edge 64. It is centered relative to the arcuate front wall 58 and is located directly across from the neck base wall 54. The exit port 36 is located and centered in the neck base wall 54.

When assembled, the top and bottom elements 42, 44 compressively capture the gasket 50 and the septum 22. The bottom element 44 is provided with a chamfer (not shown) so that it may be interference-fit together with the top element 42. The neck side and neck base walls 52, 54 together with the chamber-facing surface 34 of the septum 22 define the side walls of the injection chamber 21. The inside surface 66 f the top wall 28 and the inside-facing surface 68 of the bottom element 44 form the top and bottom walls of the injecti n chamber 21.

The seal formed by the septum 22 against the opening 26 and the seal formed by the gasket 50 between the top and bottom elements 42, 44 preferably is sufficient to withstand 45 p.s.i. air pressure without leaking for 5 seconds. The device preferably will withstand this pressure even after 500 needle punctures using a 23 gage hypodermic or 20 gage non-coring needle. Thus, if the delivery catheter connected to the injection port when implanted becomes occluded, then fluid may be introduced into the injection chamber without leaking of the fluid. A successful embodiment has been made using a septum made of silicone rubber, having a durometer of 50 and a puncture length of 0.240". The septum is compressed to a degree whereby the height of the septum is reduced by about 12.5%.

When used in pediatric patients, the side entry injection-port 20 has a height of about ⅜" (0.375") or less. In the embodiment described, the height is about 0.225". Preferably the volume of the injection chamber is not less than 5 microliters.

The size of the opening 26 is important. Preferably the opening 26 extends less than 180° about the periphery of the side wall 32, with the remainder of the side wall 32 being solid (except for the exit port). The solid portion of the side wall then will act as a stop for a needle inserted into the injection chamber. When the needle is inserted through the septum it will contact the inside surface the rigid side walls of the housing and will not come out the other side of the device. Further, if the opening extends too far about the periphery of the side walls it is also difficult to capture the septum and gasket under enough compression to achieve a device that will withstand the 45 PSI air pressure without leaking for five seconds. These problems are obviated somewhat as the size of the device and, correspondingly, the size of the injection chamber and the thickness of the rigid walls are increased. In the embodiment described, the opening is 0.34" across its face and 0.1" high.

It is also important that the opening be large enough so that the puncture surface of the septum, which is defined by the opening, may be located when the device is implanted. The puncture surface of the septum, therefore, should occupy a substantial portion of the projected side wall area of the housing when viewed along the centerline of the septum, as shown in FIG. 6.

As discussed above, the port outlet connector 38 and the bore 40 in the housing 24 define a combination filter system, exit port and catheter attachment site. Referring to FIGS. 7 and 8, the port outlet connector 38 is a cylindrical shaft having a main body 70, a neck 72 and a head 74. The end of the main body 70 meeting neck 72 is a straight cylinder 73 and is sized to fit snuggly in the cylindrical bore 40 in the housing 24. The remaining portion of the main body 70 extends from the housing 24 and has conventional barbs 76 for attaching a catheter (not shown). An axial bore 78 extends centrally through the main body 70 of the port outlet connector 38 from the barbed end to the neck 72.

The head 74 also is a straight cylinder. The neck 72 defines a tapering cylinder, with the larger end meeting

the head 74. The head 74 and neck 72 have a smaller diameter than that of the cylindrical bore 40 in the housing 24 into which they fit. The walls of the cylindrical bore 40 in the housing 24 and the head and neck 72, 74 define an annular space 80 communicating with the injecting chamber 21. This annular space 80 also communicates with the axial bore 78 in the main body 70 via a transverse bore 82 through the neck 72. Thus, fluid injected into the injection chamber 21 flows through the annular space 80, into the transverse bore 82, then into the axial bore 78 and finally into the catheter (not shown). The catheter delivers the fluid to the appropriate body location.

Referring to FIG. 9, the filter space 84 between the terminal end 86 of the head 74 and the neck base wall 54 of the injection chamber 21 defines the injection port filter. As shown in FIG. 9, the terminal end 86 of the head 74 is positioned flush with the neck base wall 54 of the injection chamber 21. The peripheral surface of the terminal end 86 of the connector head 74 may be smooth such that the filter space 84 is an open ring. Alternatively, as shown in FIG. 10 the peripheral surface of the terminal end 86 of the head 74' may be notched so that a ring of holes 88 (FIG. 11) rather than an open ring defines the filter.

Preferably the cross sectional filter area (the area of the ring shown in FIG. 9 or the sum of the area of the individual holes shown in FIG. 11) is greater than the cross-sectional area of the exit and delivery path (the smaller of the transverse bore, the axial bore and the catheter inside diameter). Fluid restriction is removed under these conditions. If the cross-sectional filter area is less than the cross-sectional area of the exit and delivery path, then preferably the walls of the head 74 and neck 72 taper quickly from the terminal end 86 of the head 74 to relieve fluid restriction.

In the embodiment described, the port outlet connector 38 is welded to the bore 40, the weld having a maximum width 0.050". The welded assembly does not leak air when tested at 45 PSI for 5 seconds.

The filter of the invention is extremely simple to manufacture as only two parts are required. It is particularly useful for the small side-entry injection port because it simplifies the difficulties involved with manufacturing, manipulating and attaching a small, separate part. In particular, it eliminates manufacturing and attaching a small filter as a separate element of the injection port. It should be understood however, that the filter may be used in any injection port regardless of size and further may be useful in devices other than injection ports.

Referring to FIG. 12, the side entry injection port 20 may be provided with a suture-tab 90. The suture tab may be made of silicone rubber and designed as a sleeve to be fitted over a catheter 92 which is in turn slipped over the barbed region of the port outlet connector 38. The suture tab 90 may be provided with suture wings 91 which extend laterally from the port outlet connector 38 when the suture tab 90 is in place. Each of the suture wings 91 may be sutured to subcutaneous tissue to secure the injection port 20 in place beneath the skin. Alternatively, the suture tab 90 may be sutured at or about a single location, on one of the suture wings only, remote from the puncture face of the septum 22 so that the face of the septum 22 may be rotated substantially parallel to the skin about the axis defined by the point of attachment. Thus, as shown in FIG. 12, the puncture surface of the septum 22 may be directed to a broader area of the skin than if no rotation were possible. In this manner, the trauma caused by the multiple puncture of the skin at a single location is reduced. Also, the movement helps to dissipate stress caused and associated tissue trauma when pressure is applied to the skin at or near the implanted device.

To implant the device, an incision is made in the skin. Then the side entry-injection port is placed beneath the skin, attaching the injection port by the suture tab to the subcutaneous tissue. The puncture surface of the septum preferably is directed away from the incision and the puncture surface of the septum is oriented substantially perpendicular to the surface of the skin. Then the incision is closed.

Accessing the implanted device is facilitated by locating the exit port directly opposite the puncture face of the septum. To access the implanted side entry injection port, the device is grasped at the exit-port between the thumb and the finger, and a needle is directed substantially parallel to the surface of the skin toward the septum by aiming at the V created by the thumb and the finger. The needle insertion pressure is discontinued when the needle abutting against the stop or solid base wall of the injection chamber is detected.

FIG. 13A illustrates the side entry port of the invention when implanted and set up for a long-term access, as compared with a typical prior art top-entry device shown in FIG. 13B. A straight needle 94 is shown accessing the side-entry injection port 20. The straight needle 94 passes substantially parallel to the surface of the skin 96, through the skin 96 and septum 22, and into the injection chamber 21. Because the needle is straight, it is inserted in a routine manner using commonly practiced venipuncture techniques. To secure the needle in place for long-term access, the needle is simply taped (shown at 97) to the skin.

In the prior art device, typically a right angle needle 98 is used for long-term access of the injection port 14. As shown, the right angle needle 98 must be inserted perpendicular to the skin 96 to access the injection chamber 16. As can be easily understood, if the distal portion 99 of the right angle needle 98 entering through the skin and septum to access the injection chamber 16 is not the proper length, the needle end 100 either will not reach the injection chamber (if the portion 99 is too short) or the right angle bend will be raised off the skin (if the portion 99 is too long). Either result is undesirable. Therefore, the right angle needle 98 must be properly sized for each patient to conform to the depth of implantation of the device and the thickness of the fatty tissue overlaying the implanted device. According to the side-entry port of the invention, a straight needle of any virtually any size may be used, and the problem of selecting the proper needle size in the prior art is obviated. Additionally, forces perpendicular to the surface of the skin have been known to cause right angle needles to back out of the injection chamber of the implanted device. Such forces perpendicular to the skin would not affect the placement of a needle accessing a side-entry injection port.

Semi-rigid catheters may be used for long term access of subcutaneous injection ports. When catheters are used with the top-entry devices of the prior art, special anti-kink brackets would be required to allow the catheter which exits perpendicularly to the skin to be bent over and taped to the skin without kinking. When a side-entry injection port is used, the catheter exits the

skin substantially parallel t the skin and the problem of kinking also is obviated.

It should be understood that other embodiments of a side-entry injection port may be substituted for the embodiment described above. For example, as shown in FIG. 14, the rigid housing 102 defining the injection chamber 104 may be characterized by a tubular wall 106 closed off at one end by a rigid wall 108 and closed off at the opposite end by a septum 110. Such a device would be implanted with the tubular wall lying substantially parallel to the surface of the skin. The puncture surface 112 of the septum 110 would lie perpendicular to the surface of the skin. The tubular wall also may be flattened to define parallel upper and lower surfaces.

Various changes and modifications to the embodiments shown in the drawings and described above may be made within the scope of the invention. It, therefore, is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted in an illustrative and not limiting sense.

What is claimed is:

1. An implantable subcutaneous injection port comprising,

a rigid housing, said housing having a substantially flat top wall, a substantially flat bottom wall and a side wall connecting the periphery of said top and bottom walls,

means defining an injection chamber in said rigid housing,

an opening in said side wall,

a septum captured by said housing and sealing said opening in said side wall, said septum having a puncture area occupying a substantial portion of the projected side wall area of the housing when viewed along the centerline of the septum, and

an exit port communicating with said chamber and passing through said side wall.

2. An implantable subcutaneous injection port as claimed in claim 1 wherein the top, bottom and side walls define the injection chamber.

3. An implantable subcutaneous injection port as claimed in claim 1 wherein the injection port has a height defined by the distance between the outside facing surfaces of the top and bottom walls, and the height is not more than ⅜".

4. An implantable subcutaneous injection port as claimed in claim 1 wherein the top wall and the bottom wall of the injection port are substantially concentric disks, with the bottom wall having a larger diameter than the top wall, and wherein the opening extends less than 180° about the side wall.

5. An implantable subcutaneous injection port as claimed in claim 4 wherein the side walls are arcuate and further comprising shoulder walls integral with at least one of said top, bottom and side walls, and wherein said shoulder walls and said arcuate side walls define an area shaped like a semicircle and said septum is sized to fit snugly and immovably within said area.

6. An implantable subcutaneous injection port as claimed in claim 1 wherein said housing is formed from two separate elements, a top element defining the top and side walls and a bottom element defining the bottom wall, the bottom element sealingly attached to the top element to capture the septum and to form the injection chamber.

7. An implantable subcutaneous injection port as claimed in claim 6 further comprising a step extending about the periphery of the side wall for receiving the bottom wall.

8. An implantable subcutaneous injection port as claimed in claim 6 further comprising a gasket sized to fit between mating surfaces of the top and bottom elements.

9. An implantable subcutaneous injection port as claimed in claims 1 r 6 further comprising a filter f r preventing particles introduced into the injection chamber from leaving the injection chamber via the exit port.

10. An implantable subcutaneous injection port as claimed in claim 1 or 6 further comprising a filter for preventing particles introduced into the injection chamber from leaving the injection chamber, and wherein said filter and said exit port are formed by,

an opening in a wall of said housing,

a shaft secured within said opening, a first portion of said shaft sized to sealingly mate with said opening and a second portion of said shaft having a cross-sectional area less than the cross-sectional area of said opening at and close to the inside surface of said wall, said second portion of said shaft and said opening defining a space and said second portion being adjacent said chamber and said first portion being closely spaced therefrom, and

a bore through said shaft communicating with said space.

11. An implantable subcutaneous injection port as claimed in claims 1 or 6 wherein the injection port does not leak air when tested at 45 p.s.i. for 5 seconds.

12. An implantable subcutaneous injection port as claimed in claim 1 further comprising means for attaching the injection port to the subcutaneous tissue at a single point remote from the septum so that the septum may be rotated substantially parallel to the skin about the axis defined by the single point of attachment when implanted.

13. An implantable subcutaneous injection port comprising,

a rigid housing defining an injection chamber, said housing having a side wall and said injection chamber having a height,

an opening in said side wall, and

a septum captured by said housing and sealing said opening in said side wall, wherein said septum has a puncture length and the puncture length of said septum is greater than the height of said housing.

14. An implantable subcutaneous injection port having a rigid housing with rigid walls defining an injection chamber, said housing having a height, an opening in said housing sealed off by a septum having an outside facing surface and a puncture length, and wherein the distance from the outside facing surface of the septum to the wall of the injection chamber opposite said septum is greater than the height of the housing.

15. An implantable subcutaneous injection port as claimed in claims 13 or 14 wherein the height of the device is about ⅜" or less.

16. An implantable subcutaneous injection port as claimed in claim 13 or 14 wherein the housing is formed of two separate elements, a top element defining the top and side walls and a bottom element defining the bottom wall, said bottom element sealingly attached to the top element to capture the septum and to form the injection chamber.

17. An implantable subcutaneous injection port as claimed in claims 13 or 14 wherein said injection port further comprises a filter for preventing particles intro-

duced into the injection chamber from leaving the injection chamber via the exit port.

18. An implantable subcutaneous injection port as claimed in claim 14, further comprising a filter for preventing particles introduced into said injecti n chamber from leaving the injection chamber via the exit port, and wherein said filter and exit port are f rmed by,

an opening in a wall of said housing,

a shaft secured within said opening, a first portion of said shaft sized to sealingly mate with said opening and a second portion of said shaft having a cross-sectional area less than the cross-sectional area of said opening at and close to the inside surface of said wall, said second portion of said shaft and said opening defining a space, and

a bore through which said shaft communicating with said space.

19. An implantable subcutaneous injection port as claimed in claim 18 wherein said shaft has a third portion extending from said housing, and wherein said third portion is barbed and comprises a catheter attachment means.

20. An implantable subcutaneous injection port as claimed in claims 13 or 14 wherein the septum has a puncture area occupying a substantial portion of the projected side wall area of the housing when viewed along the centerline of the septum, and wherein the housing has a side wall extending completely about the housing and said septum seals off an opening in said side wall extending less than 180° about said side wall.

21. An implantable subcutaneous injection port comprising,

a rigid h using defining an injection chamber, said housing characterized by a rigid tubular wall closed off at one end by a rigid side wall, and closed off at the opposite end by a septum, the length of the tubular wall being greater than the diameter of the tubular wall, and

an exit port communicating with said injection chamber through said side wall.

22. An implantable subcutaneous injection port as claimed in claim 21 wherein the diameter of the tubular wall is not more than about ⅜".

23. A method for implanting a subcutaneous injection port having an injection chamber and a septum for accessing the injection chamber comprising,

making an incision in the skin,

placing the injection port beneath the skin,

attaching the injection port to the subcutaneous tissue at a single point remote from the septum so that the septum may be rotated substantially parallel to the skin about the axis defined by the single point of attachment, and

closing the incision.

* * * * *

United States Patent [19]

Moden et al.

[11] **Patent Number: 5,013,298**

[45] **Date of Patent: May 7, 1991**

[54] **LATERALLY COMPRESSED SEPTUM ASSEMBLY AND IMPLANTABLE INFUSION PORT WITH LATERALLY COMPRESSED SEPTUM**

[75] Inventors: **James R. Moden, Bristol; Michael D. Caldwell, East Greenwich; Robert D. Moden, Warren, all of R.I.**

[73] Assignee: **Surgical Engineering Associates, Inc., Bristol, R.I.**

[21] Appl. No.: **310,637**

[22] Filed: **Feb. 13, 1989**

[51] **Int. Cl.**[5] **A61M 11/00**

[52] **U.S. Cl.** **604/93; 604/175; 604/244; 604/86**

[58] **Field of Search** 604/132, 86, 175, 244, 604/93, 185

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,762,517 8/1988 McIntyre et al. 604/175

4,781,680 11/1988 Redmond et al. ..... 604/86 X

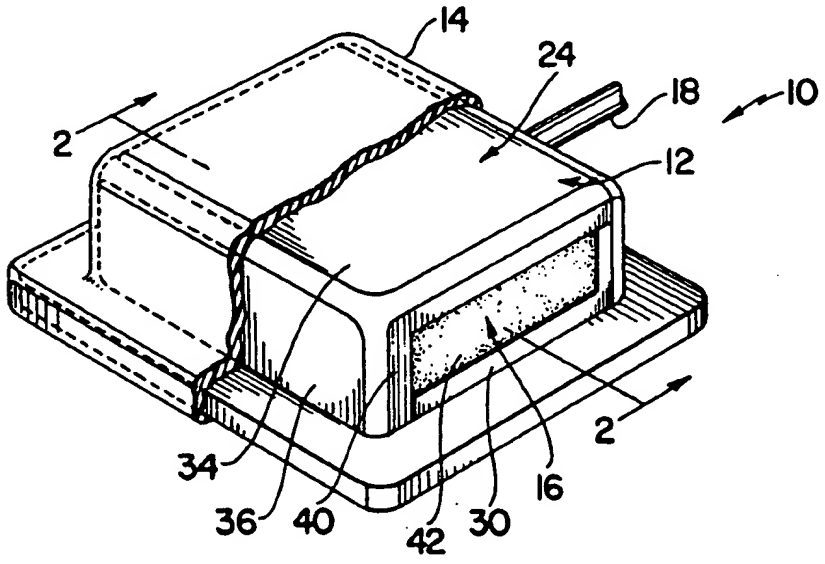
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Salter & Michaelson

[57] **ABSTRACT**

A surgically implantable infusion port includes a housing portion, a penetrable elastomeric septum portion which cooperates with the housing portion for defining an interior cavity and a catheter element which extends outwardly from the interior cavity for dispensing medication therefrom at a predetermined location in the body of a patient. The elastomeric septum portion is penetrable by a hypodermic needle for dispensing medication in the interior cavity, and it is laterally compressed to enhance the ability of the septum portion to reseal itself after being repeatedly penetrated. A septum assembly including a similar laterally compressed septum element can also be utilized as a penetrable barrier between various liquids and gases.

8 Claims, 3 Drawing Sheets



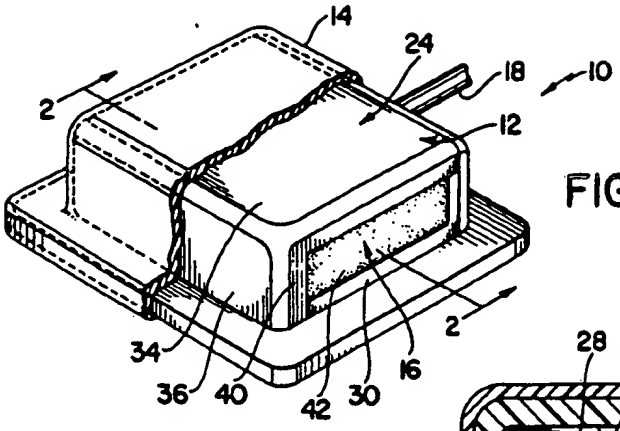


FIG. 1

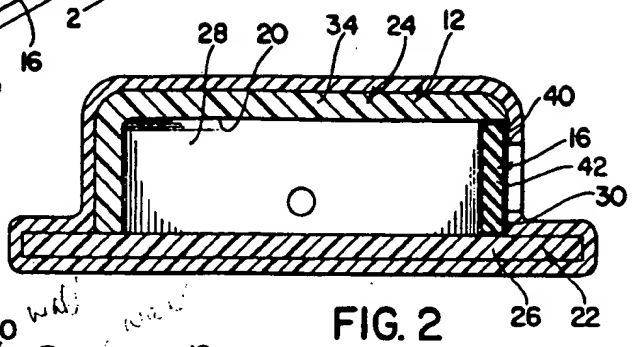


FIG. 2

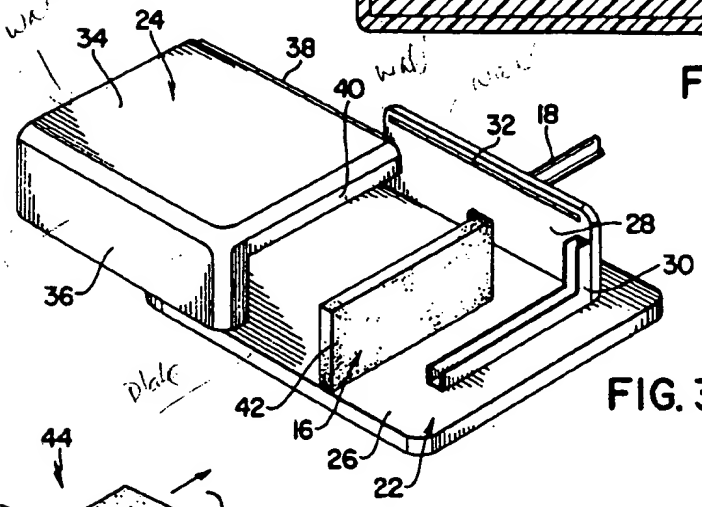


FIG. 3

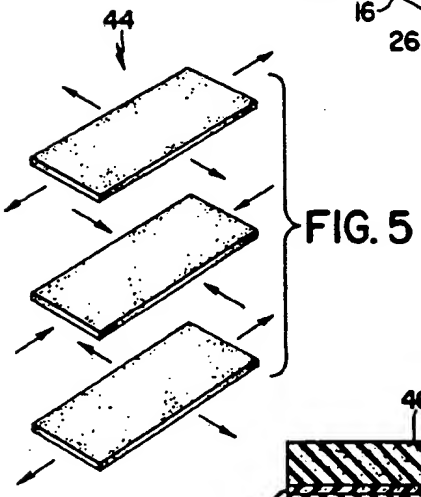


FIG. 5

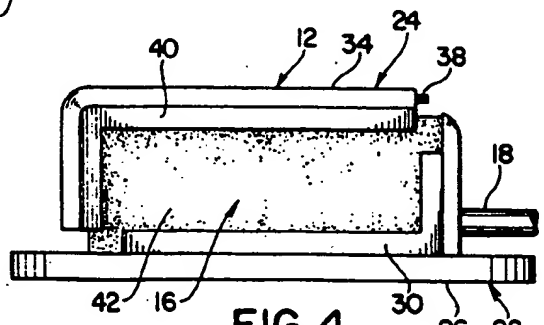


FIG. 4

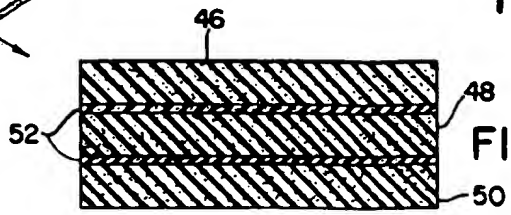


FIG. 6

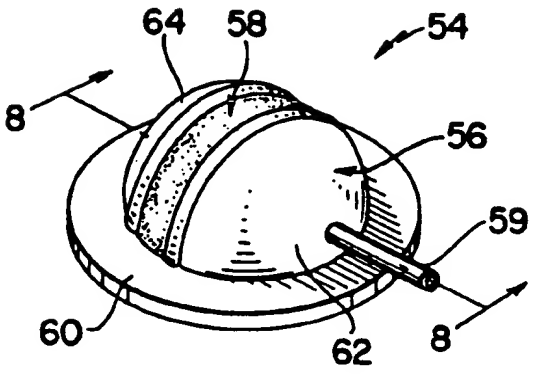


FIG. 7

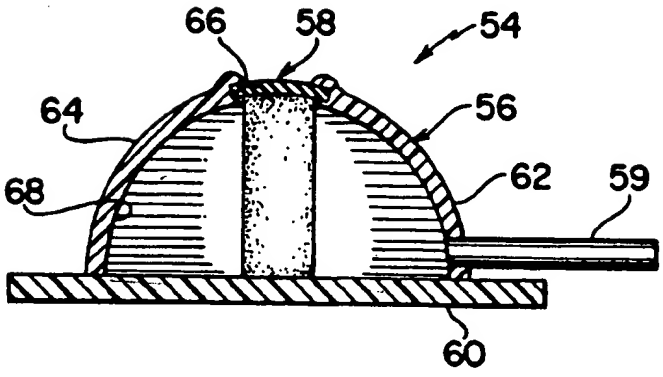


FIG. 8

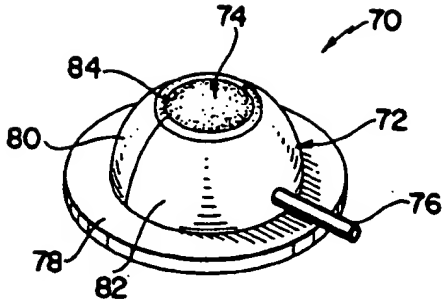


FIG. 9

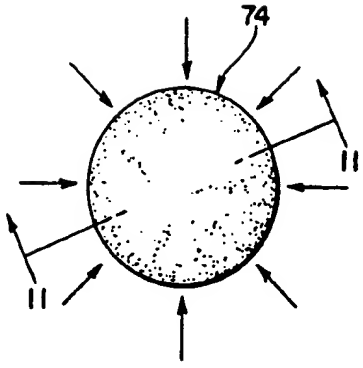


FIG. 10

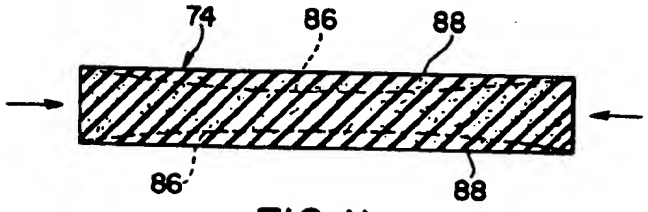


FIG. 11

LATERALLY COMPRESSED SEPTUM ASSEMBLY AND IMPLANTABLE INFUSION PORT WITH LATERALLY COMPRESSED SEPTUM

BACKGROUND AND SUMMARY OF THE INVENTION

The instant invention relates to medical apparatus and more particularly to a self-sealing laterally compressed elastomeric septum which is penetrable by a hypodermic needle or the like and to a surgically implantable infusion port which includes the septum.

Surgically implantable infusion ports have been heretofore available for a number of years, and have generally been found to be effective for dispensing medication in the bodies of patients. One of the most common types of heretofore available infusion ports comprises a rubberized base portion, a metallic housing on the base portion having an interior cavity therein and an opening at the upper end thereof, a penetrable elastomeric septum which is received in sealing relation in the opening in the housing, and a catheter which extends from the interior cavity to the exterior of the housing. In use, an infusion port of this type is normally surgically implanted in a patient so that it is positioned beneath the skin with the upper end of the housing and the penetrable septum facing outwardly, and with the catheter positioned so that it can transmit medication to a predetermined area of the patient's body, such as a large vein. Once an infusion port of this type has been surgically implanted in the body of a patient, the cavity in the housing can be filled with medication by inserting a hypodermic needle through the skin of the patient so that the tip portion of the needle penetrates the septum and passes into the interior cavity and by then dispensing medication in the cavity through the needle. In most instances, after a predetermined amount of medication has been dispensed in this manner, the hypodermic needle is removed, so that the elastomeric septum reseals itself in the area where it was penetrated by the hypodermic needle. However, it has been found that each time the septum of an infusion port of this type is penetrated by a needle, a certain amount of damage is caused to the septum and that after a septum has been repeatedly penetrated, it can lose its ability to reseal itself. It has been further found that when this occurs, it is generally necessary to surgically replace the entire infusion port.

Another type of heretofore available infusion port is disclosed in the Moden et al U.S. Pat. No. 4,710,174. This device is intended to be utilized in a similar manner to that hereinabove set forth, although it is adapted for side entry with a hypodermic needle rather than top entry, such as with the above mentioned device.

The instant invention provides an effective septum which is laterally compressed to enhance the ability thereof to repeatedly reseal itself over a prolonged period of time and an effective infusion port which incorporates the septum. Specifically, the infusion port of the instant invention comprises a housing portion having an interior cavity therein and an access opening in the housing, a septum received in sealing relation in the access opening, and a catheter which extends between the interior cavity and the exterior of the housing for dispensing medication in the body of a patient. The septum of the instant invention is made of a substantially solid elastomeric material and it has an outwardly facing surface thereon. The septum is penetrable by a hypodermic needle by inserting the needle through the utwardly facing surface of the septum. The septum is compressed by between approximately 1% and 30% in a direction which is substantially parallel to the outwardly facing uter surface thereof, and it is preferably compressed by between 5% and 10% in two substantially perpendicular directi ns, both of which are parallel to the outwardly facing surface f the septum. In one embodiment of the infusion port, the septum is of substantially circular configuration and it is compressed in at least two radially extending directions. In this embodiment, the septum is preferably substantially flat, but it is preferably at least slightly concave prior to being compressed. In another embodiment, the septum comprises first and second layers of elastomeric material, wherein the first layer is operative for applying a compressive force to the second layer in order to maintain the second layer in a compressed disposition.

It has been found that because the infusion port of the instant invention includes a laterally compressed septum, it has an increased effective life as compared to many of the heretofore available infusion ports. Specifically, it has been found that the septum of the infusion port of the subject invention has a substantially increased ability to reseal itself after repeated penetration, and that as a result, the effective life of the septum is substantially increased. Accordingly, the infusion port of the instant invention can normally remain implanted in the body of a patient for an extended period of time before surgical replacement is necessary. It has also been found that the compressed septum of the instant invention can be effectively utilized in a variety of other applications to provide a resealable barrier between two fluids, including liquids and/or gases. For example, the compressed septum can be effectively utilized as a penetrable barrier for dispenser bottles of the type commonly utilized for filling hypodermic syringes.

Accordingly, it is a primary object of the instant invention to provide an effective infusion port having a laterally compressed septum.

Another object of the instant invention is to provide an infusion port comprising a septum having an enhanced ability to reseal itself after being repeatedly penetrated with a hypodermic needle.

Other objects, features and advantages of the invention shall become apparent as the description thereof proceeds when considered in connection with the accompanying illustrative drawings.

DESCRIPTION OF THE DRAWINGS

In the drawings which illustrate the best mode presently contemplated for carrying out the present invention:

FIG. 1 is a perspective view of a first embodiment of the infusion port of the instant invention;

FIG. 2 is a sectional view taken along line 2—2 in FIG. 1;

FIG. 3 is an exploded perspective view thereof;

FIG. 4 is an end elevational view thereof;

FIG. 5 is an exploded perspective view of a septum;

FIG. 6 is an enlarged sectional view of the septum;

FIG. 7 is a perspective view of a second embodiment of the infusion port;

FIG. 8 is an enlarged sectional view taken along line 8—8 in FIG. 7;

FIG. 9 is a perspective view of a third embodiment of the infusion port;

FIG. 10 is a top plan view of the septum thereof; and

FIG. 11 is an enlarged sectional view taken along line 11—11 in FIG. 10.

DESCRIPTION OF THE INVENTION

Referring now to the drawings, a first embodiment of the infusion port of the instant invention is illustrated in FIGS. 1-4 and generally indicated at 10. The infusion port 10 is adapted to be surgically implanted in the body of a patient for dispensing medication therein, and it comprises a housing generally indicated at 12, an outer casing 14 on the housing 12, a septum 16, and a catheter 18. The septum 16 is received in sealing relation in an access opening in the housing 12 so that it cooperates with the housing 12 to define an interior cavity 20, and the casing 14 provides a cushioned outer casing on the housing 12 in order to reduce patient discomfort. The catheter element 18 is assembled with the housing 12 so that it communicates with the cavity 20, and it extends outwardly from the housing 12 for dispensing medication at a predetermined location in the body of the patient. The septum 16 is adapted to be penetrated by a hypodermic needle in order to introduce medication into the cavity 20 so that the medication can be dispensed at the desired location in the body of the patient through the catheter element 18.

The housing 12 comprises first and second housing sections generally indicated at 22 and 24, respectively, which are preferably made of a suitable plastic material and receivable in assembled relation to define the housing 12. The first housing section 22 includes a bottom wall 26, an apertured, upstanding first sidewall 28 on the bottom wall 26, and an angled channel member 30 which extends along the bottom wall 26 and then upwardly along the inner side of the first sidewall 28. An elongated slot 32 is formed along the upper edge of the first sidewall 28. The second housing section 24 comprises a top wall 34, a second sidewall 36, which depends from the top wall 34, and a third sidewall (not shown) which also depends from the top wall 34. An elongated tongue 38 is formed along one edge of the top wall 34, and an angled channel member 40 extends along the underside of the top wall 34 at the end thereof opposite the third sidewall (not shown), and then downwardly along the inner side of the second sidewall 36. The first and second housing sections 22 and 24 are receivable in assembled relation so that the tongue 38 is received in the groove 32 and so that the housing sections 22 and 24 cooperate to define the housing 12. When the housing sections 22 and 24 are assembled in this manner, the channel members 30 and 40 cooperate to define an opening for receiving the septum 16 and for maintaining it in a laterally compressed disposition.

The septum 16 is preferably made of a nontoxic, solid, elastomeric material, such as a silicone rubber, having a Shore A durometer of between 30 and 90 (preferably between 40 and 70). The septum 16 is of substantially flat, rectangular configuration, and it includes a substantially flat outwardly facing outer surface 42. The septum 16 is assembled between the first and second housing sections 22 and 24, respectively, so that it is received in the channel members 30 and 40 thereof, respectively. In this connection, as illustrated in FIG. 4, the septum 16 is dimensioned so that as it is assembled between the first and second housing sections 22 and 24, respectively, it is compressed in both a first direction which is substantially parallel to the surface 42 and extends between the first and second sidewalls 28 and 36, and a second direction which is substantially parallel to the surface 42 and extends between the top and bottom walls 34 and 26, respectively. The septum 16 is dimensioned so that it is compressed by between 1% and 30% (preferably between 5% and 10%) as the housing sections 22 and 24 are assembled together.

The catheter element 18 is preferably made of a suitable nontoxic, elastomeric material, such as a silicone rubber, and it is attached to the first sidewall 28 so that it communicates with the cavity 20 and extends outwardly from the housing 12 for dispensing medication in the body of a patient.

The casing 14 is preferably also made of a suitable silicone rubber, and it extends over all of the outer surfaces of the housing 12 to provide a cushioned outer covering therefor in order to reduce patient discomfort.

In use, the infusion port 10 is surgically implanted in the body of a patient, and the catheter element 18 is positioned so that it can be utilized for dispensing medication in a predetermined area of the patient's body, such as in a large vein. Thereafter, medication can be introduced into the infusion port 10 by inserting a hypodermic needle through the adjacent area of the patient's skin so that the tip of the needle passes through the septum 16 and into the cavity 20. Once the desired amount of medication has been dispensed in the cavity 20, the hypodermic needle can be withdrawn from the septum 16 and removed from the patient. In this regard, because the septum 16 is laterally compressed, it is able to effectively reseal itself after being repeatedly punctured so that the infusion port 10 has a substantially increased effective life.

A precompressed septum assembly which can be alternatively utilized in an infusion port, such as the infusion port 10, is illustrated in FIGS. 5 and 6 and generally indicated at 44. The septum assembly 44 comprises a first compression layer 46, a septum layer 48 and a second compression layer 50, all of which are made from a suitable solid, elastomeric material, such as silicone rubber having a durometer of between 30 and 90. The compression layers 46 and 50 are secured to the septum layer 48 with adhesive layers 52 comprising a suitably known adhesive. However, during assembly of the first and second compression layers 46 and 50 with the septum layer 48, the compression layers 46 and 50 are longitudinally and transversely stretched in directions which are substantially parallel to the main planar surfaces thereof, whereas the septum layer 48 is preferably but not necessarily both longitudinally and transversely compressed in directions which are substantially parallel to the main planar surfaces thereof. Accordingly, after the first and second layers 46, and 50 have been secured to the septum layer 48 with the adhesive 52, the first and second compression layers 46 and 50 cooperate to apply compressive forces to the septum layer 48. In this connection, once the septum assembly 44 has been formed in this manner, the septum layer 48 is normally maintained in a disposition wherein it is compressed by between 1% and 30% (preferably between 5% and 10%). Thereafter, the septum assembly 44 can be assembled in an infusion port in a manner which does not require additional compression.

A second embodiment of the infusion port of the instant invention is illustrated in FIGS. 7 and 8, and generally indicated at 54. The infusion port 54 comprises a housing generally indicated at 56, a septum generally indicated at 58, and a catheter element 59. The housing 56 comprises a substantially flat, base por-

tion 60 and a split dome-shaped portion comprising a pair of dome sections 62 and 64. The dome sections 62 and 64 are preferably made of a suitable plastic material and they are received on the base portion 60 so that they cooperate to define an elongated arcuate opening therebetween for containing the septum 58. In this connection, channels 66 are formed in the opposed edges of the dome sections 62 and 64 for receiving and containing the septum 58 so that it cooperates with the housing 56 for defining an interior cavity 68. The septum 58 is preferably also made of a solid elastomeric material having a durometer of between 30 and 90 (preferably between 40 and 70), and it is dimensioned so that when it is received in the channels 66 it is compressed in a direction which extends between the dome sections 62 and 64, i.e., in a lateral direction which is substantially parallel to the outer surface of the septum 58. The septum 58 is compressed by between 1% and 30% and preferably by between 5% and 10% when it is assembled between the dome sections 62 and 64. The catheter element 59 is secured to the dome section 62 so that it communicates with the interior cavity 68 and it extends outwardly from the housing 56 for dispensing medication in the body of a patient.

In use, the infusion port 54 is surgically implanted in the body of a patient so that the catheter element 59 is properly positioned to dispense medication at a predetermined location in the body. Thereafter, medication can be introduced into the cavity 68 by passing a hypodermic needle through the adjacent area of the patient's skin and through the septum 58. When the hypodermic needle is thereafter removed, the laterally compressed septum 58 is able to effectively reseal itself so that it can be repeatedly punctured over a prolonged period of time.

A third embodiment of the infusion port of the instant invention is illustrated in FIGS. 9–11, and generally indicated at 70 in FIG. 9. The infusion port 70 comprises a housing generally indicated at 72, a septum generally indicated at 74, and a catheter element 76. The housing 72 and the septum 74 cooperate to define an interior cavity for receiving medication therein, and the catheter element 76 communicates with the cavity for dispensing medication therefrom at a predetermined location in the body of a patient.

The housing 72 is preferably made of a suitable plastic material or a metal, and it comprises a substantially flat, circular base portion 78 and a pair of dome sections 80 and 82 which cooperate to define a rounded dome having a substantially circular opening 84 at the upper end thereof. The upper extremities of the dome sections 80 and 82 define an inwardly facing circular channel (not shown) for receiving and containing the septum 74. The septum 74 is of substantially circular configuration, and it is made of an elastomeric material, such as silicone rubber, having a Shore A durometer of between 30 and 90 (preferably between 40 and 70). As illustrated schematically in FIG. 10, the septum 74 is compressed in a plurality of radial directions. In this connection, the septum 74 is compressed by between 1% and 30% (preferably between 5% and 10%), and it is maintained in a compressed disposition by the dome sections 80 and 82. As illustrated in FIG. 11, the septum 74 is preferably formed so that before it is placed under compression, its side faces are at least slightly concave as indicated by the dotted lines 86, and it is compressed so that it is deformed to the point where its opposite side faces are substantially flat and parallel as indicated by the solid lines 88. As a result, the entire septum 74 can be effectively maintained in a compressed disposition without causing any portions thereof to be placed under tension due to distortion. The catheter element 76 is preferably made of a suitable elastomeric material, such as silicone rubber, and it is received in the dome section 82 so that it extends outwardly therefrom for dispensing medication from the interior cavity defined by the housing 72 and the septum 74.

The infusion port 70 is also adapted to be installed in the body of a patient in the manner hereinabove set forth with respect to the infusion ports 10 and 54. Further, because the septum 74 is maintained in a compressed state, it is effectively able to reseal itself each time it is punctured by a hypodermic needle so that the infusion port 70 can remain in the body of a patient over a prolonged period of time.

It is seen therefore that the instant invention provides an effective infusion port for dispensing medication in the body of a patient. The septa 16, 58 and 74 of the infusion ports 10, 54 and 70, respectively, and the septum 44 are all maintained under sufficient compression to enable them to effectively reseal themselves after they have been repeatedly penetrated by hypodermic needles. As a result, the septa 16, 44, 58 and 74 have extended effective life cycles so that infusion ports in which they are installed can remain implanted in the bodies of patients for extended periods of time. Hence, for these reasons, it is seen that the instant invention represents a significant advancement which has substantial merit in the medical art.

While there is shown and described herein certain specific structure embodying the invention, it will be manifest to those skilled in the art that various modifications and rearrangements of the parts may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.

What is claimed:

1. In an implantable infusion port for dispensing medication in the body of a patient including a housing having an access opening therein, a septum made of a substantially solid elastomeric material received in said access opening and cooperating with said housing for defining a substantially closed interior cavity, said septum having an outwardly facing outer surface thereon and being penetrable by a hypodermic needle by inserting said needle through said outwardly facing surface, and catheter means communicating with said cavity for dispensing medication therefrom into the body of said patient, the improvement comprising said septum having an inwardly facing surface which faces substantially opposite from said outwardly facing surface, said infusion port further comprising first and second elastomeric layers secured in overlying relation on said outwardly facing surface and said inwardly facing surface, respectively, said first and second compression layers cooperating to compress said septum by between 1% and 30% in a direction which is substantially parallel to said outwardly and inwardly facing surfaces.

2. In an implantable infusion port for dispensing medication in the body of a patient including a housing having an access opening therein, a septum made of a substantially solid elastomeric material received in said access opening and cooperating with said housing for defining a substantially closed interior cavity, said sep-

tum having opposite outwardly and inwardly facing surfaces and being penetrable by a hypodermic needle by inserting said needle through said outwardly facing surface, and catheter means communicating with said cavity for dispensing medication therefrom into the body of said patient, the improvement comprising said outwardly and inwardly facing surfaces being substantially parallel, said septum being compressed by between 1% and 30% in at least first and second substantially perpendicular directions which are substantially parallel to said outwardly and inwardly facing surfaces, said septum being formed so that each of said outwardly and inwardly facing surfaces is at least slightly concave prior to compressing said septum in said first and second directions.

3. In the infusion portion of claim 2, said septum being compressed by between 1% and 30% in each of said first and second substantially perpendicular directions.

4. In the infusion port of claim 3, said septum being compressed by between 5% and 10% in each of said first and second directions.

5. A precompressed septum assembly comprising an elastomeric septum layer having substantially parallel opposite first and second surfaces and first and second elastomeric compression layers secured in overlying relation on said first and second surfaces, respectively, said septum layer and said first and second compression layers being penetrable by a hypodermic needle, said first and second compression layers cooperating to compress said septum layer by between 1% and 30% in a direction substantially parallel to said first and second surfaces.

6. In the septum assembly of claim 5, said first and second compression layers cooperating to compress said septum layer by between 1% and 30% in two perpendicular directions which are substantially parallel to said first and second surfaces.

7. A precompressed septum assembly comprising an elastomeric septum layer having opposite substantially parallel first and second surfaces and an elastomeric compression layer secured in overlying relation on the first surface of said septum layer, said septum layer and said compression layer being penetrable by a hypodermic needle, said compression layer maintaining said septum layer in a disposition wherein it is compressed by between 1% and 30% in a directi n substantially parallel to said first and second surfaces.

8. In an implantable infusion port for dispensing medication in the body of a patient including a housing having an access opening therein, a septum made of a substantially solid elastomeric material received in said access opening and cooperating with said housing for defining a substantially closed interior cavity, said septum having opposite outwardly and inwardly facing surfaces and being penetrable by a hypodermic needle by inserting said needle through said outwardly facing surface, and catheter means communicating with said cavity for dispensing medication therefrom into the body of said patient, the improvement comprising said housing including a shell portion of rounded dome-like configuration and a substantially flat base portion, said shell portion including first and second shell portion sections which cooperate to substantially define said shell portion, said first and second shell portion sections being received on said base portion and cooperating therewith to define said interior cavity, said first and second shell portion sections cooperating to define said access opening and cooperating to compress said septum in said access opening by between 1% and 30% in a direction substantially parallel to said outwardly facing surface, said access opening being in the configuration of an arcuate band extending across said dome-like shell portion.

* * * * *

US005741228A

United States Patent [19]

Lambrecht et al.

[11] Patent Number: 5,741,228

[45] Date of Patent: Apr. 21, 1998

[54] IMPLANTABLE ACCESS DEVICE

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[73] Assignee: Strato/Infusaid

[21] Appl. No.: 390,014

[22] Filed: Feb. 17, 1995

[51] Int. Cl.[6] A61M 11/00

[52] U.S. Cl. 604/93; 604/891.1; 604/256; 251/149.3

[58] Field of Search 604/256, 93, 167, 604/891.1, 175; 251/149.3

[56] References Cited

U.S. PATENT DOCUMENTS

4,645,495	2/1987	Vaillancourt	604/180
4,654,033	3/1987	Lapeyre et al.	604/175
5,053,013	10/1991	Ensminger et al.	604/167
5,057,084	10/1991	Ensminger et al.	604/167
5,180,365	1/1993	Ensminger et al.	604/93
5,195,980	3/1993	Catlin	604/167
5,226,879	7/1993	Ensminger et al.	604/93
5,263,930	11/1993	Ensminger	604/93
5,281,199	1/1994	Ensminger et al.	604/93
5,308,336	5/1994	Hart et al.	604/167
5,324,270	6/1994	Kayan et al.	604/167
5,350,360	9/1994	Ensminger et al.	604/93
5,352,204	10/1994	Ensminger	604/93
5,356,381	10/1994	Ensminger et al.	604/93
5,360,413	11/1994	Leason et al.	604/249
5,417,656	5/1995	Ensminger et al.	604/93
5,476,451	12/1995	Ensminger et al.	604/93

FOREIGN PATENT DOCUMENTS

0110117	6/1984	European Pat. Off. .
0159260	10/1985	European Pat. Off. .
WO8302063	6/1983	WIPO .
WO9405246	3/1994	WIPO .
WO9405351	3/1994	WIPO .

Primary Examiner—Mark Bockelman

Attorney, Agent, or Firm—Needle & Rosenberg, P.C

[57] ABSTRACT

An implantable access device for allowing repeat access to a site, space, device, or other object, fluid, tissue or region within the body of a patient. The implantable device, in one embodiment, includes a housing having an elongated open guidance channel that leads to an entrance orifice, a valve assembly communicating with the entrance orifice, and an exit orifice. The device permits access via the percutaneous insertion of an accessing filament such as a needle through the entrance orifice and into the valve assembly, which opens to allow the passage of fluids or other filaments such as guide wires or optical fibers. The device can be used for the introduction of therapeutic agents, for the infusion or withdrawal of fluids, or for the introduction of sensing, sampling, or treatment devices to another implanted device or to regions within the patient.

7 Claims, 6 Drawing Sheets

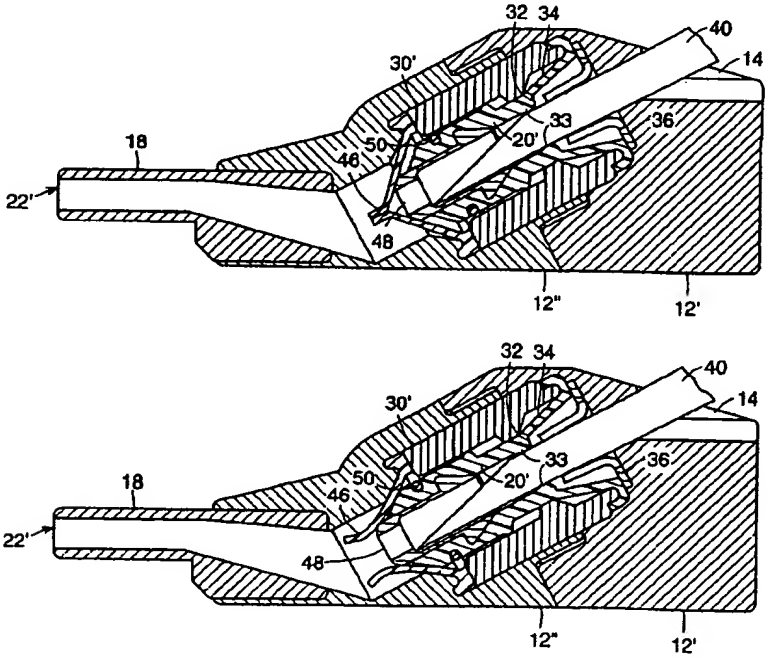


FIG. 1

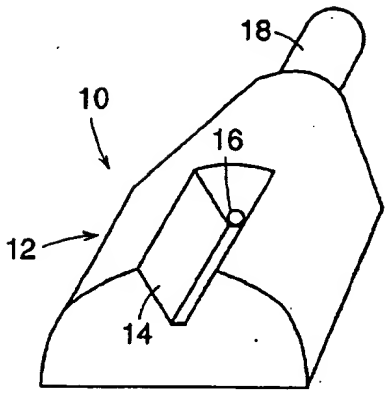


FIG. 6

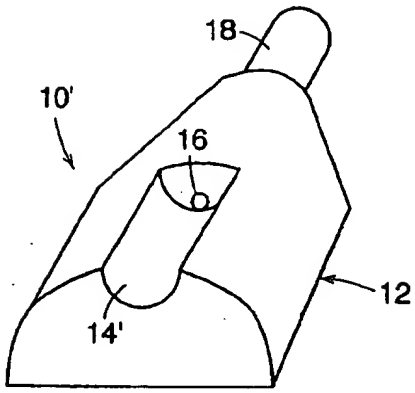
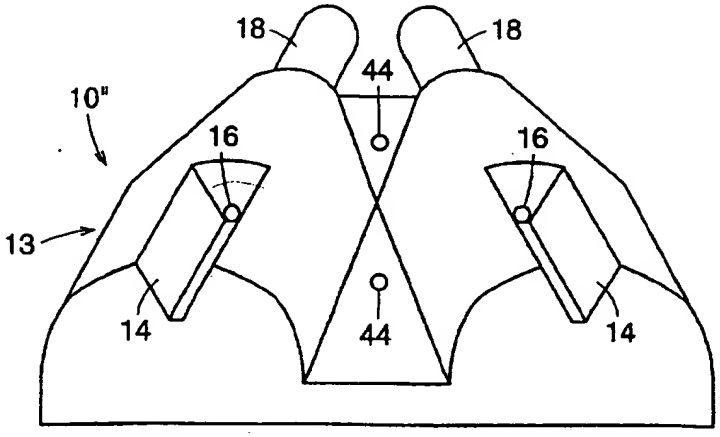


FIG. 7



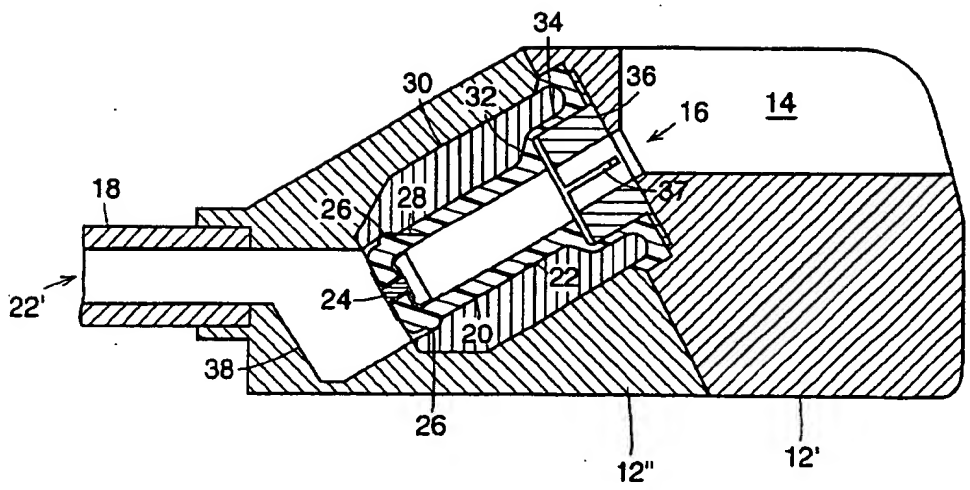


FIG. 2

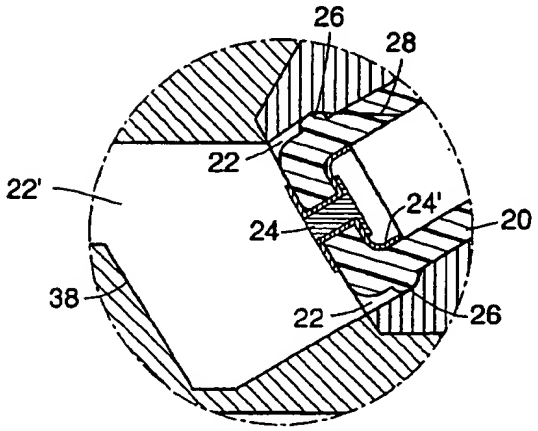


FIG. 2A

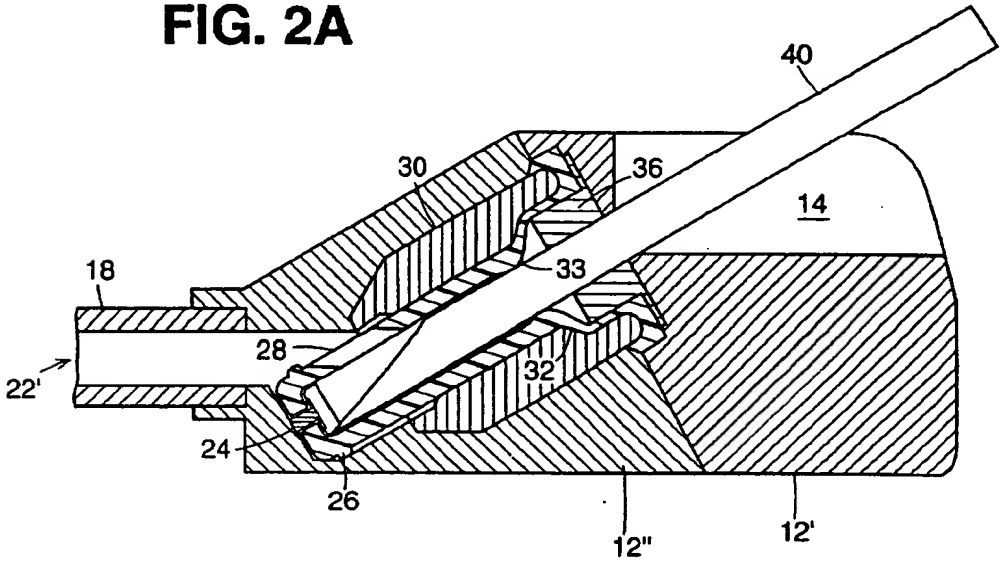


FIG. 3

FIG. 3A

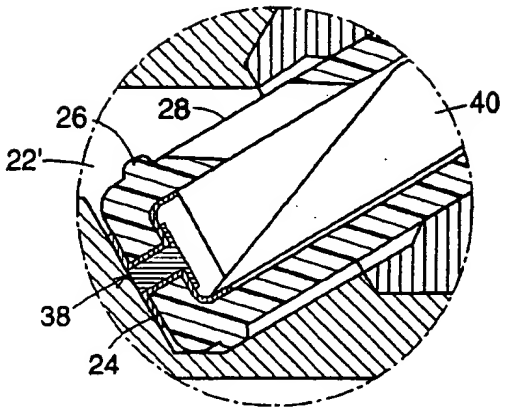


FIG. 3B

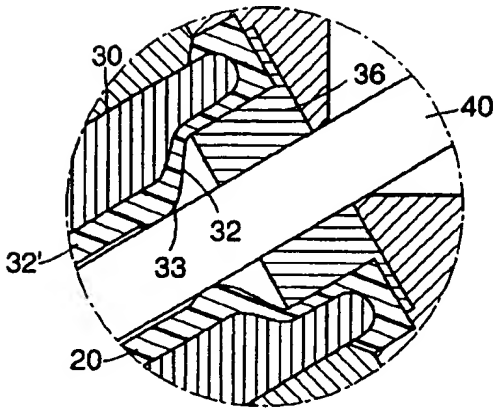


FIG. 4

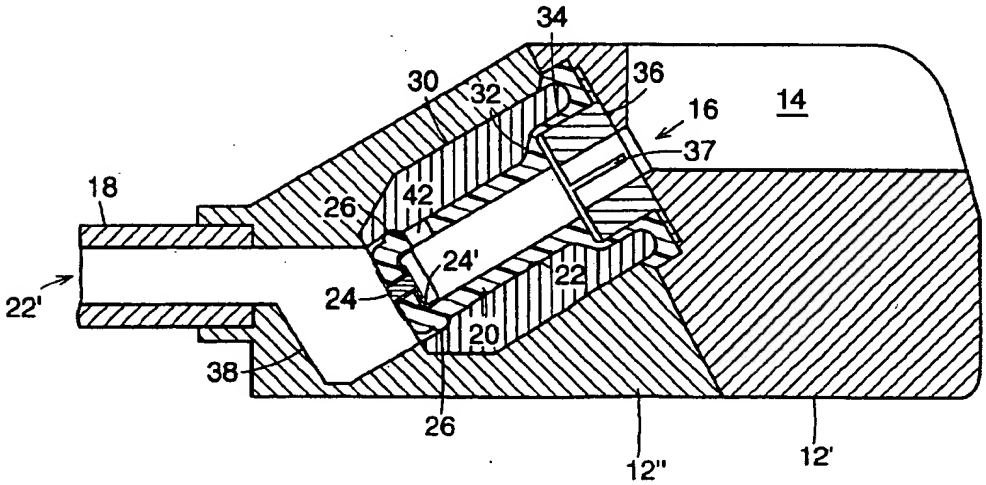


FIG. 5

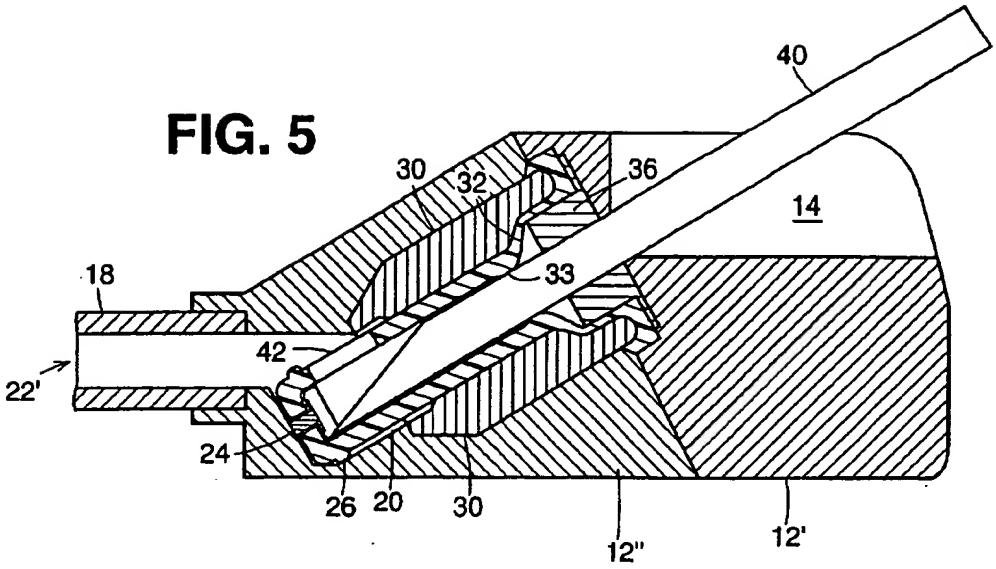

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FIG. 8

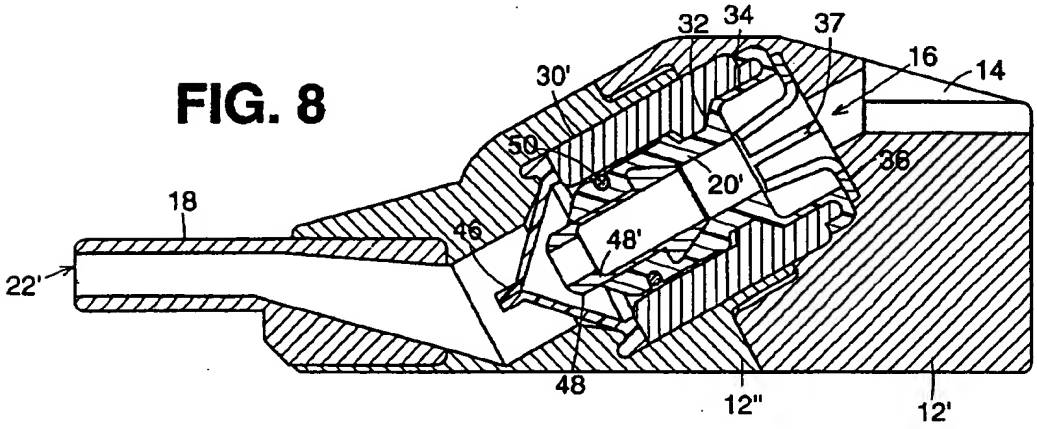
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FIG. 9

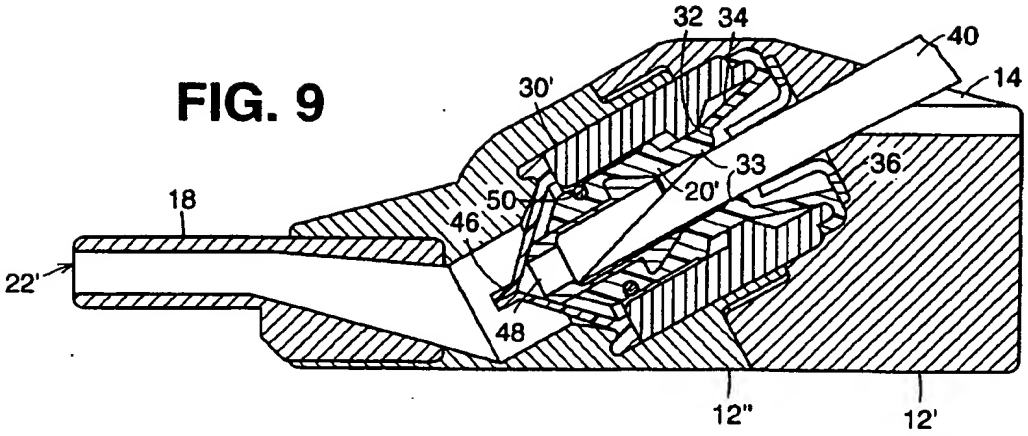
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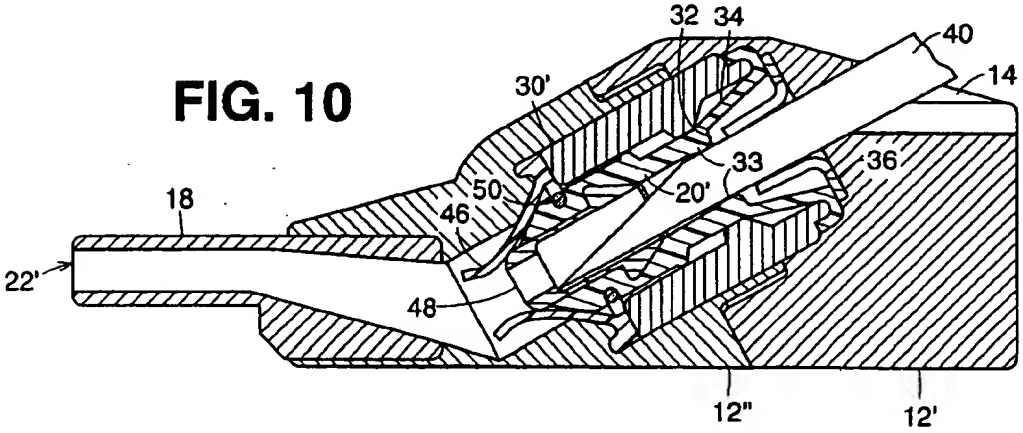
FIG. 10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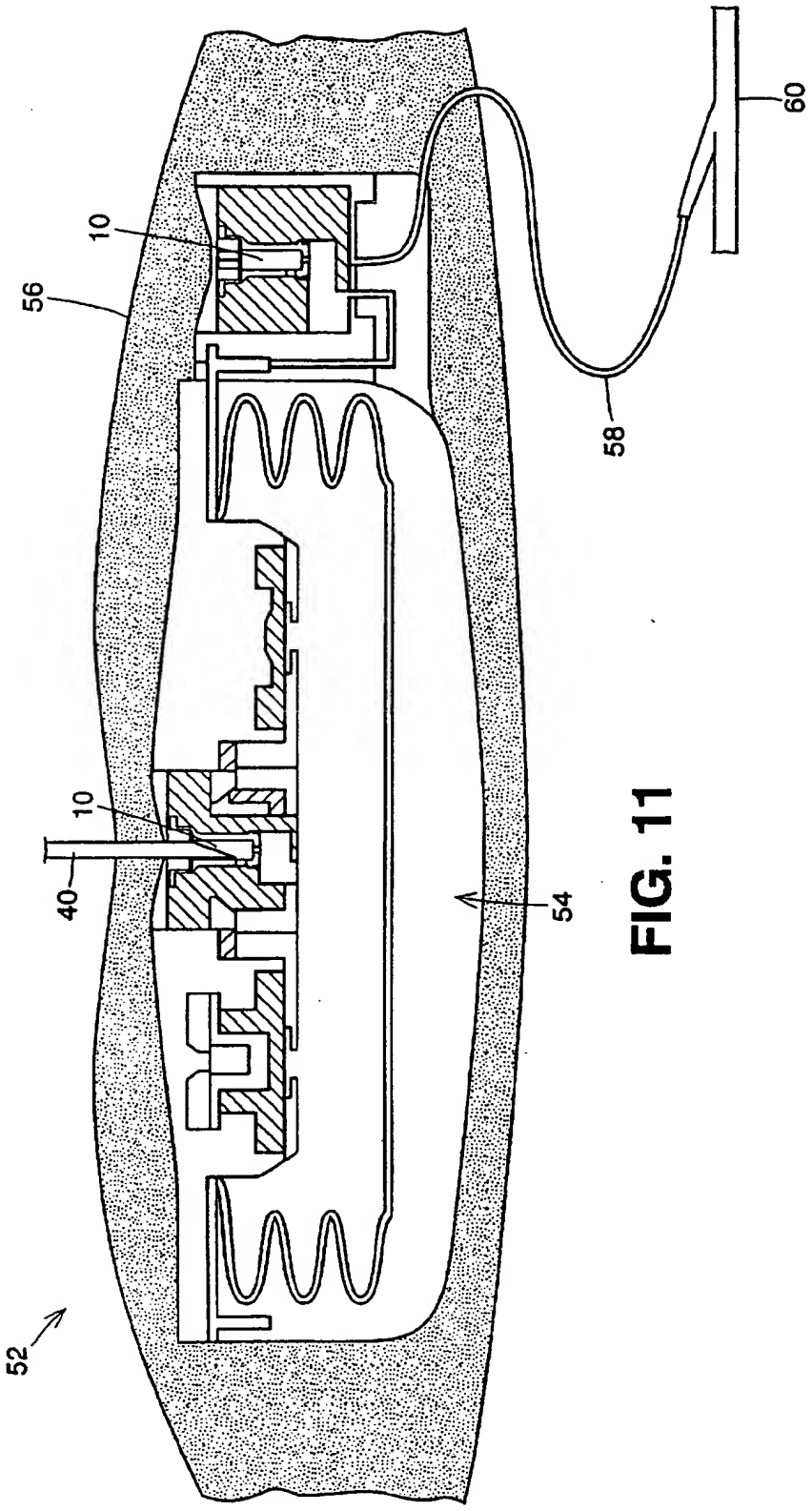

FIG. 11

IMPLANTABLE ACCESS DEVICE

BACKGROUND OF THE INVENTION

The present invention pertains generally to an apparatus for providing access to a living body. More particularly, the invention relates to an improved implantable patient access device which allows for repeated access to a region within the body of a patient.

During a course of treatment, it may be necessary to gain repeat access to specific sites, devices, tissues, or fluids within the body of a patient. This may be effected for the temporary or sustained infusion of various therapeutic agents, the removal and treatment of fluids, the injection of contrast agents, as well as the insertion of various treatment devices such as fiber-optic cameras and light sources, ultrasound probes, and thrombectomy catheters. A number of strategies are currently used to gain such access, including direct vessel cannulation, short and long term catheterization, as well as subcutaneous port and pump implantation.

Direct cannulation of a native or artificial vessel with a needle provides perhaps the least expensive and simplest form of access. However, repeat cannulation of superficial vessels has been shown to result in vessel thrombosis, and in case of hemodialysis graft cannulation, access stenosis and the formation of pseudoaneurisms. A patient's accessible vessels can quickly be eliminated by repeat direct cannulation during the course of some aggressive treatment regimens, limiting treatment options and worsening prognosis. The use of large needles also leaves behind substantial lacerations in the vessel, requiring the application of pressure for a number of minutes to regain hemostasis, particularly in the case of high flow or high pressure vessels such as arteries, central veins, and primary or prosthetic fistulas. This pressure is uncomfortable for the patient and may result in early vessel thrombosis independent of other causes.

Short and long term catheters have been used to address the many problems of direct cannulation. These transcutaneous devices are generally flexible cannulae that are inserted percutaneously into the region of interest such as a blood vessel or the peritoneal cavity. Catheters have one or more lumens through which various fluids or devices can pass. While catheters allow repeat access with a reduced risk of vessel thrombosis, they suffer from a number of significant drawbacks. Aside from being unsightly and prone to inadvertent withdrawal, catheters often have complications with infection. The location of the infection is commonly the exit site or point at which the catheter passes through the skin. This essentially open wound provides a path for various hazardous organisms to migrate into the body and cause infections, either local or systemic. Infection has also been shown by a number of authors to increase the occurrence of both catheter and vessel thrombosis, other common complications of in-dwelling catheters.

Subcutaneously implanted ports have increasingly been used as an alternative to transcutaneous catheterization. These devices provide a site beneath the skin that can be accessed by special non-coring needles through a percutaneous puncture at the time of treatment. The devices generally comprise a housing that forms a reservoir which communicates with a catheter that leads to the area requiring treatment. A self-sealing septum formed from a high density silicone elastomer spans the top of this reservoir, creating a continuous barrier against the passage of fluids such as blood that are in communication with the port. This septum is punctured by the needle to permit access to the reservoir.

Once the needle is withdrawn, the septum closes, restoring the continuous barrier. By being completely implanted (that is, requiring no open passage through the skin) ports avoid many of the infection complications of catheters. Ports are also generally better accepted by the patient because they are less obtrusive, cannot be accidentally withdrawn, and are easy to maintain.

Subcutaneously implanted ports are also used as a means of communicating with other implanted medical devices. For example, implantable infusion pumps that provide a sustained infusion of therapeutic agents into the body of a patient often use one or more integral ports as refilling and flushing sites. Various other devices, such as implanted inflatable prostheses, have exploited or may have benefited from the use of such ports as well.

Subcutaneously implanted ports do have a number of significant drawbacks that limit their application. First, their useful life is limited by the number of punctures that the septum can withstand before it leaks. Repeat access slowly degrades the silicone septum until ultimately it is unable to resist the passage of fluids or other elements that are in communication with the port. Secondly, they cannot be accessed by normal needles, requiring special, relatively expensive non-coring needles to reduce the damage done to the septum. This expense may seem minimal, but can be significant when aggressive therapies are required or when the therapies are primarily Medicare funded. Thirdly, only small needle gauges can be used even with non-coring needles because larger bore needles quickly destroy the septum. However, small needles are not appropriate for many treatments such as transfusion or hemodialysis which require high blood flows.

A series of prior art patents disclose an implantable patient access port which allows the introduction of various filaments including catheters and needles into the body of a patient without the use of a standard septum. By employing a variety of different valving mechanisms, the port presumably has broader applications to more rigorous therapies requiring frequent access or high flow, i.e. therapies previously restricted to transcutaneous catheters and direct cannulation. All of the ports illustrated and described in the patents incorporate a housing having a generally funnel-shaped entrance orifice, a valving mechanism that is opened by the accessing filament, allowing its passage, and an exit passageway.

One significant limitation of the foregoing prior concepts is in the strike area, or the region that the medical professional attempting access must hit with the accessing filament to enter the device. A large strike area is critical for simple cannulation and for allowing each insertion wound to heal before that region must be re-cannulated. By nature, to increase the strike area of a funnel such as that described in the art, one must also increase its overall size in three dimensions. A dimension of particular importance with ports is height, or depth from the skin inward. The taller a port, the more tension it places on the insertion wound, the more obvious its presence to observers, and potentially the greater chance for erosion and infection. So increasing the strike area of the funnel, increases the size of the port in three dimensions, potentially leading to complications.

The funnel-shaped entrance orifice further limits the strike area by providing only a single focal point or entry point for the accessing filament. Because the filament is always focused to the same site, the same tissue proximal to that entry site must be traumatized during each access. Repeat trauma to tissue can lead to devascularization and necrosis, creating a potential site for infection.

Another limitation of prior art concepts is the durability of the valve assembly when sharp needles or trocars are used for access. While there exist various concepts that allow access by either flexible filaments such as catheters or rigid filaments like needles, all of the valve assemblies allowing access specifically by rigid filaments are either subject to direct contact with the sharp tip of the accessing needle promoting wear or do not specifically seal around the accessing filament before the valve assembly is open or before it closes. In certain known devices, elastomeric members which form the valve assembly are in the direct path of the accessing needle. The hole in the first elastomeric member is smaller in diameter than the accessing filament, and hence will suffer damage every time the accessing needle is inserted. This damage could ultimately lead to valve failure, which can have catastrophic consequences for the patient.

In certain prior art designs, movement of the valve components is directly linked with movement of the sealing components so that creation of a seal around the accessing filament requires the valve to be opened. The leaflets of the valve are either in direct sealing engagement with the filament sealing element or the motions of the two elements are directly linked through an intervening rigid member. These designs imply that some throw or partial opening of the valve is required before the seal is created around the accessing filament or, more importantly, that flow is potentially allowed through this partially open valve and around the accessing filament until the valve has been opened far enough to generate an effective seal. This could potentially lead to the repeat formation of hematomas or passage of other fluids into the tissue surrounding the device as a result of access.

The primary objective of the present invention is to provide an implantable patient access device which overcomes many of the deficiencies of prior art ports. Specifically, in one embodiment, the implantable access device that forms this invention employs an open guidance channel that allows for increases in accessing filament strike area without increasing the overall height of the device. Further, the device employs a valve assembly that provides access to the patient while at all times maintaining a fluid tight seal around the accessing filament, normally a needle. The valve assembly does not allow contact of the accessing filament's sharp leading edges, particularly in the case of a needle, with any soft elastomeric member of the valve assembly. In this way, the valve assembly allows repeat access by standard needles of either small or large gauge, eliminating many of the access problems that have limited the use of standard ports with septums and some other prior art devices. Further, the valve assembly ensures that a seal around the accessing filament will be formed prior to the valve assembly opening to allow access to the patient. This is accomplished in one embodiment of the invention by ensuring that less movement of the accessing filament is required to create a seal about the filament than is required to begin opening the valve, and in another embodiment of the invention by completely decoupling creation of the seal from motion of the valve. The assembly thus ensures that there is no leakage of fluids around the accessing filament at any time during access. Other advantages of the present invention are described below.

SUMMARY OF THE INVENTION

The present invention is directed toward an implantable patient access device comprising a housing having at least one entry port and at least one exit port with a passageway extending therebetween, with the housing further comprising an elongated open guidance channel disposed therein communicating with the entry port, with the channel having a substantially constant cross sectional area and with the channel further being adaptable to receive a filament for guiding the filament toward and into the entry port, and with the housing further including a valve assembly disposed in the passageway, the valve assembly adapted to be activated by the filament after passage of the filament through the entry port, the valve assembly being normally closed but adapted to be opened by the filament to allow access to the patient or to a site, space, device, or other object, tissue, or fluid within the patient by the filament. The valve assembly comprises a sealing element and a valve disposed in the passageway, with the sealing element first creating a seal about the filament before the valve assembly opens to allow access to the patient by the filament. The sealing element maintains the seal about the filament until after the valve assembly closes. The channel might have a generally V-shaped cross section or it might have a generally U-shaped cross section such as a parabola. The valve might comprise a miter valve or a slit valve, with each valve adapted to be opened by movement of the filament into the valve assembly. Alternatively, the valve might comprise in combination a plug seated in sealing engagement within the passageway and a slit valve, the plug and the slit valve being forced from sealing engagement with the passageway by movement of the filament through the passageway. Additionally, the valve might comprise a plug seated in sealing engagement within the passageway and an opening proximate to the plug such that when the plug is forced from sealing engagement with the passageway by movement of the filament through the passageway the opening allows access to the patient or site, space, device, or other object, tissue, or fluid within the patient by the filament. The sealing element comprises an elastomeric member with a first and second end and an open conduit therebetween, with the first end being substantially fixed in position within the housing and with the second end having a resilient cap affixed thereto, the cap being adapted to withstand repeat contact with the filament, resisting passage of the filament such that when the filament is advanced through the conduit the filament makes contact with the cap causing the elastomeric member to stretch and collapse around the filament. The elastomeric member has an outer dimension, the outer dimension at a first location having a first magnitude which decreases to an outer dimension of a second magnitude at a second location, the decrease corresponding to a decrease in dimension of the passageway such that when the elastomeric member is stretched by advancement of the filament, the larger outer dimension of the elastomeric member is compressed against the accessing filament within the smaller dimension of the passageway. The housing further comprises means for retaining an accessing filament in a fixed position within the housing. The exit port is adapted to be connected to a catheter, a graft or an implanted medical device.

The invention further embodies an implantable patient access device comprising a housing having at least one entry port and at least one exit port with a passageway extending therebetween, the entry port being adapted to receive a filament for passage into the passageway, the housing further including and disposed in the passageway a valve assembly comprising a valve and a sealing element, the valve assembly adapted to be activated by the filament after passage of the filament through the entry port whereupon a seal, independent of activation of the valve, is created by the sealing

element about the filament before the valve opens to allow access to the patient or site, space, device, or other object, tissue, or fluid within the patient by the filament. The valve might comprise a miter valve or a slit valve, with each valve adapted to be opened by movement of the filament into the valve assembly. The valve might comprise an elastomeric plug seated in sealing engagement within the passageway, the plug being forced from sealing engagement with the passageway by movement of the filament through the passageway. The sealing element comprises an elastomeric member with a first and second end and an open conduit therebetween, the first end being substantially fixed in position within the housing and the second end having a resilient cap affixed thereto, the cap being adapted to withstand repeat contact with the filament, resisting passage of the filament such that when the filament is advanced through the conduit the filament makes contact with the cap causing the elastomeric member to stretch and collapse around the filament. The elastomeric member has an outer dimension, the outer dimension at a first location having a first magnitude which decreases to an outer dimension of a second magnitude at a second location, the decrease corresponding to a decrease in dimension of the passageway such that when the elastomeric member is stretched by advancement of the filament, the larger outer dimension of the elastomeric member is compressed against the accessing filament within the smaller dimension of the passageway creating a seal about the filament. The housing might further comprise means for retaining an accessing filament in a fixed position within the housing. The filament might be a needle having a point and the housing might further include means for guiding the needle through the conduit and into the resilient cap such that the point of the needle contacts only the resilient cap. The exit ports in these devices are adapted to be connected to a catheter, a graft or an implanted medical device.

The invention additionally embodies an implantable patient access device comprising a housing having a plurality of entry ports and a plurality of exit ports with a passageway extending between each entry port and each exit port, with the housing further comprising a plurality of elongated open guidance channels disposed therein, each of the guidance channels communicating with an entry port, each of the guidance channels having a substantially constant cross sectional area, with each of the guidance channels further being adaptable to receive a filament for guiding the filament toward and into an associated entry port, the housing further including a valve assembly disposed in each passageway, the valve assembly adapted to be activated by the filament after passage of the filament through the entry port, the valve assembly being normally closed but adapted to be opened by the filament to allow access to the patient or site, space, device, or other object, tissue, or fluid within the patient by the filament.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic perspective view of a first embodiment of an implantable patient access device in accordance with the principles of the present invention and illustrating an elongated open generally V-shaped entrance guidance channel.

FIG. 2 is an enlarged longitudinal sectional view of the device depicted in FIG. 1.

FIG. 2A is a further enlarged view of a portion of the device illustrated in FIG. 2 showing a partial view of the valve assembly of the device.

FIG. 3 is a view much like that of FIG. 2 but further showing the valve assembly of the device being activated by an accessing filament.

FIG. 3A is an enlarged view much like that depicted in FIG. 2A but further showing the valve assembly after activation by the accessing filament.

FIG. 3B is an enlarged view of another portion of the device illustrated in FIG. 3 showing a seal created about the accessing filament.

FIG. 4 is a view substantially like that of FIG. 2 but depicting an alternate embodiment of the valve of the invention.

FIG. 5 is a view substantially like that of FIG. 3 but depicting the valve arrangement of FIG. 4.

FIG. 6 is a view much like that of FIG. 1 but showing an elongated open generally U-shaped entrance guidance channel.

FIG. 7 is a view similar to FIG. 1 but illustrating a device having multiple entrance guidance channels and exit ports.

FIG. 8 is a view much like that of FIGS. 2 and 4 but depicting an alternate embodiment of a valve assembly with the valve assembly closed.

FIG. 9 is a view much like that of FIG. 8 but depicting a seal created about the accessing filament but with the valve closed.

FIG. 10 is a view much like that of FIG. 9 with the seal maintained but the valve open.

FIG. 11 schematically depicts an embodiment of the present inventive device as an integral part of an implanted medical apparatus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The description herein presented refers to the accompanying drawings in which like reference numerals refer to like parts throughout the several views. Referring to FIG. 1, in accordance with the principles of the present invention, there is illustrated a schematic perspective view of a first embodiment of an implantable patient access device **10**. The excess device **10** includes a housing **12** having defined therein an elongated open guidance channel **14** communicating with entry port **16** of the housing. In this figure the guidance channel is shown to be of a generally V-shaped configuration but other configurations would be possible. Port **16** in turn is in fluid communication with housing exit port **18**. The internal structure of device **10** will be shown in greater detail in subsequent views.

Turning now to FIG. 2, there is depicted an enlarged longitudinal sectional view of implantable patient access device **10** depicted in FIG. 1. Here there is shown an elastomeric member **20** disposed in passageway **22** of device **10**. Elastomeric member **20**, in this embodiment, includes a plug **26**, a slit valve **28** and terminates in a cap **24**. Cap **24** may be titanium, stainless steel or any other suitable resilient metal. Elastomeric member **20** is positioned within a housing insert **30**. Housing insert **30** is employed for ease of manufacture, but it should be understood that it could also be integral in the geometry of housing **12**. Here housing **12**, for ease of manufacture, is shown to be composed of part **12'** and part **12"**. Elastomeric member **20** further has a transition region **32** along which the outer diameter of the elastomeric member **20** decreases from a first larger diameter to a second smaller diameter. The interaction between the elastomeric member **20**, specifically its transition region **32**, and the housing insert **30** will create a seal around an accessing

filament as will be further described below. Elastomeric member 20 has a substantially thinner walled section 34 above transition region 32. Also within passageway 22 is a filament retention piece 36. Exit port 18 extends from housing part 12" and forms lumen 22' which is in fluid communication with passageway 22. Exit port 18 is adaptable to be coupled to a catheter, graft, another device or conduit that is within and/or in communication with the body of a patient. Also shown here as part of housing part 12", is a limiter 38 which stops the downward movement of the activated valve assembly. FIG. 2A is an enlarged view of the left portion of FIG. 2. FIG. 2A shows the plug 26 at the distal end of the elastomeric member 20 in a sealing engagement with passageway 22, and slit valve 28 in a closed position. FIG. 2A also depicts cap 24 and filament landing 24'.

Turning now to FIG. 3, there is shown the patient access device of FIG. 2 with an accessing filament 40 opening the plug 26 and the slit valve 28. Preferably the filament is substantially rigid. Typically the filament would be a needle but a catheter or other substantially rigid member could be used. Before movement of plug 26 out of passageway 22 and the opening of slit valve 28 which would allow communication between filament 40 and lumen 22', a seal 33 is first created about filament 40. Seal 33 is maintained at all times when plug 26 and slit valve 28 allow communication between the filament 40 and lumen 22' and the seal is released only after plug 26 returns to a sealing engagement within passageway 22. FIG. 3A shows an enlarged view of the valve comprising plug 26 and slit valve 28 in an open position. FIG. 3B is an enlarged view which shows in greater detail the seal 33 about accessing filament 40. Seal 33 is generated when the transition region 32 of elastomeric member 20 is pulled into the smaller diameter 32' of housing insert element 30, compressing the elastomeric member 20 against the accessing filament 40. Further in FIG. 3B is shown the filament retention piece 36 engaging accessing filament 40. The filament retention piece 36 is configured with an inner dimension smaller than the outer dimension of the accessing filament 40, such that as the accessing filament 40 is introduced into entry port 16, the filament retention piece 36 expands and applies a force against the accessing filament 40 to resist its withdrawal from entry port 16. Filament retention piece 36 may employ a strain release slot or slots 37 to tune the force applied to accessing filament 40 and increase its useful life span. FIGS. 4 and 5 are substantially the same as FIGS. 2 and 3, the primary difference being that slit valve 28 has been replaced by an opening 42 located in elastomeric member 20.

FIG. 6 is substantially the same view as that shown in FIG. 1 except that here the device has been designated 10' and the guidance channel 14' has a generally parabolic or generally U-shaped cross section. A guidance channel having a flat rather than a curved bottom is also considered to be of a generally U-shaped configuration. The generally U-shaped configuration is but one of the many possible configurations suitable for the elongated open guidance channel of the invention.

FIG. 7 depicts a dual patient access device 10" configuration with two complete devices (each having any of the valve assemblies described herein) fixedly coupled in a housing 13 to simplify the implantation of two devices. FIG. 7 also shows two suture holes 44 for anchoring the device to the patient. Suture holes 44 are only one of the many possible anchoring means for these devices. While not shown, any of the devices that form this invention can employ an anchoring means such as suture holes 44.

FIGS. 8 through 10 depict another embodiment of the present invention which employs a duck bill or miter valve 46 in place of plug 26 and slit valve 28 or opening 42. Cap 48, having a filament landing or strike area 48', has replaced cap 24. A fastener 50 assists in maintaining the coupling between elastomeric member 20' and cap 48. Elastomeric member 20' has all of the attributes of elastomeric member 20. FIG. 8 depicts the valve assembly prior to activation. Also shown in FIG. 8, is housing insert 30' which is substantially like housing insert 30. The remaining structural elements are like those herein described in respect to the other embodiments of the invention. FIG. 9 additionally depicts an accessing filament 40 which moves cap 48 and elastomeric element 20' to create a seal 33 about filament 40 before valve 46 is opened. FIG. 10 shows further advancement of filament 40 and cap 48 which opens valve 46 to provide access to a patient or a site, space, device, or other object, tissue, or fluid within the patient. As shown here and as is shown in all other embodiments of the invention, seal 33 is created about the accessing member before the respective valve is opened, the seal is maintained during the time that the valve is open and the seal is not released until after the valve is closed.

Turning lastly to FIG. 11, there is shown a schematic view of device 10 of the present invention as an integral functioning part of an implantable medical apparatus 52, such as a sustained infusion pump 54. Here two devices are shown. However, it should be understood that one or a number of devices could be employed, such as 10, 10', 10". In this view, pump 54 has been implanted below skin line 56 of a patient. Additionally shown is catheter 58 fluidly coupled to lumen 22' (not depicted in this view). The catheter is in fluid communication with a vessel 60, however, communication could be with a site, space, tissue, fluid, organ or another implanted device. Although not shown in this view, it also should also be understood that, like in FIG. 11, each of the devices of FIGS. 1–10 are adaptable for inclusion as an integral part of an implanted medical apparatus or adaptable for independent implantation under the skin of a patient for communication with a site, space, tissue, fluid, vessel, organ, or the like.

An important characteristic of the various valve assemblies is the timing of the valve opening and closing relative to the seal formed around the accessing filament. Each valve assembly forms a seal around the accessing filament before the valve opens allowing access to the patient, and then releases that seal only after the valve has again been closed. This prevents any possibility of hemorrhage or reflux of fluids or gases out the device.

The open guidance channels that are part of this invention have a number of advantages over the funnels described in the prior art. First, they allow for increases in strike area without an increase in overall device height. With a device of the configuration shown in FIG. 1, the strike area is increased simply by increasing the length of the device. Another advantage of the channel is that it allows the device to better simulate a natural vessel both in shape and the way in which it is accessed. This may make the device and its use more readily apparent to the accessing nurse or physician. Finally, an elongated open channel could allow for multiple entry sites along the channel's length, unlike a funnel which is limited to a single focal point. By accessing different entrance orifices during a treatment that requires repeat access procedures, trauma to the same tissue can be minimized relative to the funnel with its single focal orifice.

The device in FIG. 3 consists of a three-part housing, a needle retention piece, and a wedge seal and plug valve

assembly. A first piece 12' of the housing could be made of a resilient material such as titanium that could endure frequent contact with the sharp tip of an accessing filament such as a needle. The guide channel that is an integral part of piece 12' is one of the many possible open channel forms described by this invention. The channel depicted in FIG. 3 could be employed as a filament guide. The base of this guide channel could be sloped from a first end towards the entrance orifice at an angle suitable for allowing the accessing filament to slide easily upon contact as well as for decreasing the overall volume of the device. The walls of this channel may be, to name but a few configurations, vertical, sloped or rounded. Extending laterally from either side of piece 12' at its base could be two suture loop attachment sites for facilitating fixation of the device within the body. Any suitable number of attachment points can be used. FIG. 7 illustrates but one potential fixation configuration. Alternatively, the exterior surface of the housing can be roughened or porous, promoting tissue ingrowth to help fix the device within the patient.

A second piece 12" of the housing can be made either of a resilient material or of a more easily molded material such as plastic. This piece forms much of the flow path for the fluids that could be infused or removed through the complete device. To decrease the necessary flush volume and the risk of fluid pooling, the diameter of the flow path is closely matched to the diameter of the accessing filament. A third piece 18 is a simple tube insert that provides a surface along which a catheter or graft may be joined with the patient access device. Again, this piece could be constructed from either a resilient or moldable plastic material. The exit port may provide communication with an implantable medical device and may be of another configuration more suitable to optimizing its function in a certain application. Filament retention piece 36 is a simple tube with a flanged end. It should be constructed of a resilient material capable of withstanding frequent contact with a sharp accessing filament. The tube is slotted along all or part of its axial length and is of a diameter to some degree less than the diameter of the accessing filament. Hence when the accessing filament such as a needle is inserted, the tube expands elastically, applying a force normal to the filament about its circumference. This force creates a friction that is sufficient to retain the filament in an engaged position during the access procedure.

The wedge seal and plug valve assembly consists of three functional parts. The first is a tube-like structure (20) formed from an elastomer such as silicone rubber. The second is a small cap (24) formed of a resilient material which is fixed to the distal end of the tube, but can be fixed to the tube at any appropriate site. The third piece is a simple insert (30) that is either a separate piece as depicted or is part of the geometry of the second piece of the housing. The tube is clamped into place at its proximal end just beyond the entrance orifice and filament retention piece. The tube fits within the internal structure of the insert. The outer diameter of the tube mirrors the interior shape of the insert along most of its length, being greatest at the most proximal end, narrowing along a short transitional length, and then remaining constant up to a point near the distal end. It should be understood that the term proximal, when referring to FIG. 2 for example, is that location towards the right of the figure while the term distal refers to that location towards the left of the figure. At the distal location of the tube, an annular plug (26) bulges radially from the tube to a diameter greater than the corresponding interior diameter of the insert. This plug acts as the valve, sealing against fluids or gases when the tube is recessed within the insert and the plug is compressed against the insert's interior. Just above this plug is either a hole or slit through the wall of the tube which becomes a passageway for fluids or filaments when the valve is open. The tube has an internal diameter that is larger than that of the specified accessing filament. The proximal portion has the largest internal diameter to allow the filament retention piece to fit recessed within the tube. This portion of the tube also has the thinnest wall, making it the most flexible section. When an accessing filament is inserted into the device it makes contact only with the retention piece and the cap at the tube's distal end. Further advancement of the filament causes the elastomeric tube to stretch, particularly in the thinner proximal section. This stretch pulls the thicker transitional length of tube into the narrower portion of the insert, compressing the tube between the wall of the insert and the circumference of the filament. This compression creates a seal. When the annular plug at the distal portion of the tube is pushed beyond the distal portion of the insert, the opening above this plug is exposed to the exit port allowing fluids to be infused and withdrawn or instruments to be inserted into the body of the patient.

The valve only opens once the seal has been created about the accessing filament and closes before that seal is broken. This is ensured by the travel necessary to push the annular plug out of sealing engagement with the interior wall of the insert. This travel is specified to be longer than the travel necessary to generate a seal around the accessing filament.

The device depicted in FIGS. 8–10 uses a miter or duck bill valve (46) as the valving element. Typically the miter valve comprises elastomeric elements or components. The valve is opened as the cap at the distal end of the elastomeric tube is pushed into the valve by the advancing filament or needle. This cap would again be formed from a resilient material such as stainless steel, titanium or other suitable metal. The cap has a simple step decrease in internal diameter from the proximal portion to the distal portion. The larger diameter allows passage of certain specified filaments or needle gauges, while the smaller diameter acts to limit passage of those filaments or needles, but allows for fluid flow.

The duck bill valve may have some advantages over the side hole valve of FIG. 4 or the slit valve of FIG. 2. It provides a more direct and potentially smoother fluid flow and instrument insertion pathway. This may ease insertion of various devices and allow for higher infusion flow rates at lower pressures. Another distinct advantage of this valve assembly is that creation of the seal about the accessing filament requires no motion of the valve. By decoupling the sealing element from the valve and by separating the two elements, the design ensures that the seal will be created about the filament before the valve opening is initiated.

The use of a channel in these devices allows the overall device to better simulate a natural artery or vein. By running down the central axis of the device, a channel, as herein described, would allow the accessing medical professional to access the port in much the same way they access peripheral vessels, i.e. by placing fingers on either side of the vessel and sticking for its center. The length of this channel can be chosen to fit the requirements of the specific therapy, allowing for an increase in overall strike area by increasing the size of the implantable access device in only a single dimension.

We claim:

1. An implantable access device comprising a housing having at least one entry port and at least one exit port with a passageway extending therebetween, said housing further

comprising an elongated open entrance guidance channel disposed therein having a tenth and communicating with said entry port, said channel having a substantially constant transverse cross sectional area substantially along the length, with substantially constant cross sectional area substantially along the length, with said channel further being adaptable to receive a filament for guiding said filament toward and into said entry port, and with said housing further including a valve assembly disposed and into said entry port, and with said housing further including a valve assembly disposed in said passageway, said valve assembly adapted to be activated by said filament after passage of said filament through said entry port, said valve assembly being normally closed but adapted to be opened by said filament to allow access through said exit port, wherein said valve assembly comprises a sealing element and a valve disposed in said passageway, with said sealing element being positioned closer to said entry port than is said valve, said filament and said sealing element coacting to first create a seal about said filament before said valve opens to allow said access, and wherein said sealing element comprises an elastomeric member with a first end and a second end and an open conduit therebetween, said first end being substantially fixed in position within said housing and said second end having a resilient cap affixed thereto, said cap being adapted to withstand repeat contact with said filament, resisting passage of said filament such that when said filament is advanced through said conduit the filament makes contact with said cap causing said elastomeric member to stretch and collapse around said filament.

2. The device according to claim 1 wherein said elastomeric member has an outer dimension, said outer dimension at a first location having a first size which decreases to an outer dimension of a second size at a second location, said decrease corresponding to a decrease in dimension of said passageway such that when said elastomeric member is stretched by advancement of said filament, the larger outer dimension of said elastomeric member is compressed against said accessing filament within the smaller dimension of said passageway.

3. An implantable access device comprising a housing having at least one entry port and at least one exit port with a passageway extending therebetween, said entry port being adapted to receive a filament for passage into said passageway, said housing further including and disposed in said passageway a valve assembly comprising a valve and a sealing element, said sealing element comprising an elastomeric member with a first and second end and an open conduit therebetween, said first end being substantially fixed in position within said housing and said second end having a resilient cap affixed thereto, said cap being adapted to withstand repeat contact with said filament, resisting passage of said filament such that when said filament is advanced through said conduit the filament makes contact with said cap causing said elastomeric member to stretch and collapse around said filament, said valve assembly adapted to be activated by said filament after passage of said filament through said entry port whereupon a seal, independent of activation of said valve, is created by said sealing element about said filament before said valve opens to allow access through said exit port.

4. The device according to claim 3 wherein said valve comprises a miter valve.

5. The device according to claim 3 wherein said housing further comprises means for retaining an accessing filament in a fixed position within said housing.

6. The device according to claim 3 wherein said exit port is adapted to be connected to a catheter, a graft, or an implanted medical device.

7. The device according to claim 3 wherein said filament is a needle having a point and wherein said housing further includes means for guiding said needle through said conduit and into said resilient cap such that said point of said needle contacts only said resilient cap.

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